

This response was submitted to the consultation held by the Nuffield Council on Bioethics on Give and take? Human bodies in medicine and research between April 2010 and July 2010. The views expressed are solely those of the respondent(s) and not those of the Council.

Progress Educational Trust

Question 1

Our belief is not so much that there are additional types of human bodily material that could raise ethical concerns, but rather that types of human bodily material can be distinguished and categorised in ways other than those used in the consultation paper. For instance, human bodily material can be organised according to prevalent social attitudes. Such an approach might give us three categories. First, ontologically significant material (for example whole organs and gametes), which elicits high levels of public concern. Second, ontologically neutral material (such as hair and nail clippings), which elicits low levels of public concern. Third, ontologically repugnant material (such as urine and faeces), which elicits little or no public concern as long as it is efficiently disposed of. These categories relate to the ethical weight commonly attached to bodily material, and to the corresponding ways in which relevant public policy is developed. For example, ontologically neutral and ontologically repugnant materials are often regarded as property for purchase and sale, with little objection. The law has recognised that regenerative body materials such as hair (see the UK's case *R v Herbert* (1961) 25 *Journal of Criminal Law* 163) and urine (see the UK's case *R v Welsh* [1974] RTR 478) can be the subject of property rights and are capable of being stolen. By contrast, ontologically significant material tends to be expressly prohibited from proprietary status (see the USA's case *Moore v Regents of University of California* [1990] 51 *Cal. 3d* 120; 271 *Cal. Rptr.* 146, and the provisions of the UK's Human Tissue Act 2004). In the UK's case *Yearworth and others v North Bristol NHS Trust* ([2009] EWCA Civ 37), the Court of Appeal found in favour of six patients, in a group of legal claims made over sperm donations lost due to a freezer breakdown at Southmead Hospital in 2003. Five men and the widow of a sixth man sought compensation over sperm samples which were obtained before infertility-inducing cancer treatments, and were lost due to the negligent actions of North Bristol NHS Trust. The patients' claims were originally rejected at Exeter County Court, on the basis that sperm donations are no longer a part of a patient's body and can be likened to toenail clippings or cut hair. But the Court of Appeal overturned that decision. The Court of Appeal held that to claim for loss or damage to property, a person must have had either legal ownership of, or a possessory title to, the property when damage occurred. The law has, to some extent, been refined in relation both to ownership of a human corpse and to parts of it. But the law has been silent about parts or products of a living human body, probably due to the fact that until recently, science and medicine did not endow parts or products of a living human body with any value or significance. According to the Court of Appeal, developments in science and medicine require a reanalysis of the common law's treatment of and approach to ownership of parts or products of a human body, whether for an action in negligence or otherwise. For the purposes of their

negligence claims, the claimants in *Yearworth v North Bristol NHS Trust* had ownership of the sperm which they had ejaculated – the sole object of which had been that, in certain events, it might later be used for their benefit. The patients' rights to use of the sperm were limited to an extent, by the conditions within the UK's Human Fertilisation and Embryology Act 1990. But the absence of their ability to direct the use of the sperm did not derogate from their ownership of it. By its provisions for consent, the Act assiduously preserved the claimants' ability to direct that the sperm was not to be used in a certain way. While the licence holder (the hospital) had duties which might conflict with the claimants' wishes, no person (whether human or corporate) other than each claimant had any rights in relation to the sperm produced. On the facts as known there was bailment of the sperm by the claimants to the hospital unit, and (subject to resolution of factual matters) the unit was liable under the law of bailment as well as under that of tort. More generally, the ruling means that those who give sperm samples before they become infertile can rely on the promise to maintain their sample. This ruling represents a significant enhancement of the legal status of patients with respect to their donated gametes. Donated gametes are now legally considered to remain the property of the donor so long as it is the donor's intention to have the sample retained (allowing for statutory limits on storage). As the judgment states: 'The sperm retained a significant property, namely that, although...suspended by having been frozen, it remained in essence biologically active, a living nexus with the men whose bodies had generated it.' These ontological attitudes are subject to change. For example, umbilical cord blood was previously routinely disposed of and considered ontologically neutral, whereas it is now clinically valuable and therefore ontologically significant (see the journal article 'Umbilical cords: turning garbage into clinical gold', C Thompson, 'Science', 12 May 1995). There is also the issue of the emotive advertising used by commercial cord blood banks, which typically charge in the region of £1,500 for a 20-year storage term. Despite the rise of private 'for-profit' cord blood banks, there is little evidence to suggest that personally stored blood will ever be used. This has led bodies such as the Royal College of Midwives (see 'Commercial cord blood collection: guidance paper 1a and position statement 1', Royal College of Midwives, 2002) and the Royal College of Obstetricians and Gynaecologists (see 'Opinion paper 2: umbilical cord blood banking', Scientific Advisory Committee, Royal College of Obstetricians and Gynaecologists, June 2006) to declare that storage for autologous (personal) use is not to be recommended at this time.

Question 2

There are several types of human bodily material that should be regarded as special. Three examples are gametes, stem cells and mitochondria. Gametes (sperm, eggs and embryos) and reproductive tissues are special, inasmuch as they can lead to conception – in other words, to the creation of an individual whose genetic complement is partially derived from the gamete donor. This genetic

connection between individuals is of potential medical, emotional and legal significance. Genetic connections are medically significant, because characteristics (including disorders) can be transmitted via genetic inheritance. Genetic connections are emotionally significant, because many people ascribe an automatic emotional significance to their genetic relatives (although this is not always the case and it may not be as common a sentiment in future, so such significance should not be taken as axiomatic). Genetic connections are legally significant, because following the removal in 2005 of entitlement to donor anonymity in the UK, individuals conceived through gamete donation can receive identifiable information about the donor once aged 18 and may try to contact the donor. Stem cells are special, inasmuch as their potency is different from that of other cells in the body. A cell's potency is its potential to differentiate into different types of cells. Stem cells are typically totipotent (meaning that they can develop into an entire organism) or pluripotent (meaning that they can give rise to any fetal or adult cell type). By contrast, other cells in the body are typically multipotent or oligopotent (meaning that they can give rise to a limited number of cell types), or else unipotent (meaning that they can give rise to one cell type). This, together with the fact that it is not always possible to obtain stem cells from adults (they must sometimes be obtained from embryos, fetuses, umbilical cords or amniotic fluid), means that stem cells may pose different challenges and require different considerations from other types of human bodily material. Mitochondria are special because they contain genetic information in the form of DNA. This mitochondrial DNA is involved in processes that are related to, but distinct from, the processes associated with the more familiar DNA that is contained within the nucleus of human cells. Evolutionarily, mitochondria are enslaved primitive bacteria with their own genetic code. They replicate independently of the nucleus, and carry no genetic information that defines any specifically human attribute. Like nuclear DNA, mitochondrial DNA is involved in processes of genetic inheritance. But unlike nuclear DNA, which contains genes derived from both of a person's genetic parents, mitochondrial DNA is derived only from a person's mother (except in very rare instances – see 'Paternal inheritance of mitochondrial DNA', Marianne Schwartz and John Vissing, 'New England Journal of Medicine', 22 August 2002). The number of genes contained within mitochondria is far smaller than the number of genes contained within the cell nucleus. Nonetheless, abnormalities in mitochondrial DNA can lead to debilitating and sometimes fatal disorders, such as mitochondrial myopathy. The transmission of such disorders from women to their offspring, has eluded biomedical remedy until recently. A pioneering technique known as pronuclear transfer (see the journal article 'Pronuclear transfer in human embryos to prevent transmission of mitochondrial DNA disease', Mary Herbert, Douglass Turnbull et al, 'Nature', 6 May 2010) involves fertilising the egg of a woman with abnormal mitochondrial DNA, and then transferring the nucleus of the resulting zygote into the egg of a donor with normal mitochondrial DNA. This achievement elicited some ethical concerns, from people who claimed that the resulting (healthy) child had 'three parents'. These concerns are unfounded. Since

mitochondria carry no genetic information that defines any specifically human attribute, it is as erroneous (if not more so) to say that a child following pronuclear transfer has 'three parents' as it would be to say that the recipient of a donated organ has 'four parents'. Nonetheless, misapprehensions about mitochondria are noteworthy in that they illustrate the importance of making a correct distinction between mitochondrial DNA and nuclear DNA. Most people's assumptions about DNA, genes and inheritance in humans is restricted to nuclear DNA, whereas mitochondrial DNA requires more flexible thinking.

Question 3

In the case of ontologically significant material (see our answer to Q1), the need for consent is fundamental. This is the case whether human bodily material is provided during life or after death, notwithstanding the fact that contemporaneous consent cannot be sought from the dead. One example of ontologically significant material is gametes (sperm and eggs), and in considering gametes it is instructive to compare the three high-profile examples of *Natalie Evans* (in the European Court of Human Rights' case *Evans v United Kingdom* (Application no 6339/05) Judgment. Strasbourg, 10 April 2007), *Diane Blood* (in the UK's case *R v Human Fertilisation and Embryology Authority, ex parte Blood* [1997] 2 All ER 687), and the family of *Keivan Cohen* (in Israel's case *New Family Organisation v Committee for Approving Surrogacy Agreements Tel Aviv District Court 2007*). In *Evans v United Kingdom*, Natalie Evans and her fiancé Howard Johnston received fertility treatment because she was subsequently due to undergo treatment for ovarian cancer that would render her infertile. Six embryos created in the course of the fertility treatment were placed in storage, whereupon she was treated for ovarian cancer. The relationship between Ms Evans and Mr Johnston ended and he then withdrew his consent to their fertility treatment, with the consequence that their embryos would have to be destroyed under UK law. She sought to prevent this from happening. The case went to the Grand Chamber of the European Court of Human Rights where, the judges delivered a unanimous verdict and said they 'did not consider that the applicant's right to respect for the decision to become a parent in the genetic sense should be accorded greater weight than [Howard Johnston's] right to respect for his decision not to have a genetically related child with her.' The case gave unequivocal support for one party concerned in the creation of an embryo to withdraw their consent to that embryo's storage or use in treatment or for research. The Human Fertilisation and Embryology Act 1990, as amended by the Human Fertilisation and Embryology Act 2008, provides for a 12 month cooling-off period if one party withdraws their consent while the other party (or parties) wish fertility treatment to continue. The most recent (eighth) edition of the Human Fertilisation and Embryology Authority's Code of Practice recommends that fertility clinics have 'procedures for dealing with disputes that may arise when one gamete provider withdraws their consent to the use or storage of gametes or embryos in treatment'. In the case of *R v Human Fertilisation and Embryology Authority, ex*

parte Blood, Diane Blood's husband fell into a coma, whereupon she persuaded doctors to procure and store sperm from him. He then died, and she sought to use his sperm in fertility treatment, despite the fact that he had not consented to this written while he was alive. The Court of Appeal's final judgment, in Diane Blood's favour, was based on the initial informal consent (an oral agreement) that he was said to have given while alive. In the case of *New Family Organisation v Committee for Approving Surrogacy Agreements*, Israeli soldier Keivan Cohen died from injuries sustained in combat. His parents persuaded doctors to procure and store sperm from him in the hours immediately following his death. The hospital refused to give his parents access to the frozen sperm without court approval, as under Israeli law only a spouse can make such a request, and the late soldier was unmarried. His family challenged the hospital's decision in court, claiming that it was their son's profoundest wish to have children, and showed the court video material in which he expressed his wish to start a family. The District Court of Tel Aviv ruled in the family's favour, despite no prior provisions existing in Israeli law regarding the permitted use of sperm extracted from the deceased. The ruling represents the first time that a court has approved the use of a deceased man's sperm to impregnate a woman he has never met. These three cases illustrate the importance of gamete donors and gamete recipients alike consenting to fertility treatment involving them or their bodily material. These cases also illustrate the difficulty of establishing consent retrospectively when one of the parties involved in conception is deceased, a scenario that has become increasingly likely as modern science and medicine has allowed gametes and embryos to be stored, and has allowed gametes to be obtained from the unconscious and the dead. One upshot of this is that it is important to obtain clear written consent from the living, if there is any likelihood of posthumous use of their bodily material being necessary or desirable – for example, individuals in the armed forces or in high-risk professions.

Question 4

Egg donation involves some health risks, which should be clearly explained to and understood by prospective egg donors. These include the side-effects of fertility drugs (which can include hot flushes, irritability and headaches) and the risk of developing ovarian hyperstimulation syndrome while undergoing ovulation induction (this can be a life-threatening complication). Additionally, unlike sperm (which can usually be obtained via ejaculation), eggs must be obtained via a surgical procedure. As with any surgical procedure (including procedures undergone by organ donors), there are potential risks of infection, discomfort, bleeding and injuries to internal tissues and organs (in the case of egg donation, these might include the bowels, the bladder or blood vessels). Some argue that there are broader psychological risks associated with gamete (sperm, egg and embryo) donation. We believe that these risks have been overstated, as has the emotional significance of gamete donation. Although it is true that many people ascribe an automatic emotional significance to their genetic relatives, this is not always the

case, and it may not be as common a sentiment in future. As non-traditional families become increasingly commonplace, so the assumption that genetic relationships are coterminous with family relationships may cease to be automatic. Our vocabulary may undergo corresponding changes, so that – for example – donor-conceived individuals can more easily distinguish between their father (who raised them) and their sire (who donated sperm for their conception). Before the removal in 2005 of entitlement to donor anonymity in the UK, it was argued that donor-conceived individuals with no knowledge of their genetic provenance experienced difficulties of psychology and identity. Even now that the entitlement to donor anonymity has been removed, some argue that there should be more stringent requirements imposed upon gamete donors, such as providing more information about themselves. The argument is that this would attract a higher standard of gamete donor who takes their responsibilities seriously, thus contributing to the welfare of the child conceived as a result of donation. We disagree with this argument, as we feel that it (wrongly) seeks to impose the responsibilities of parenthood upon donors. While gamete recipients of gametes should have access to all available donor information, it does not necessarily follow from this that donors should be encouraged to give all of this information. Certainly, donors should not be coerced into giving more than the rudimentary information. Even if there is no explicit coercion, there is a slippage that can occur between good or best practice, guidelines, and mandatory requirements, where the classification of a practice in one category becomes the justification for promoting it to the more binding category. It would be a mistake for the authorities to make or encourage any pejorative assumptions about the amount of information that a donor gives. For one thing, there may be good reasons for not giving certain information. For another thing, even where there are no such good reasons, the judgement as to whether comprehensiveness of donor information is an indicator of donor suitability should rest (at best) with the gamete recipient or (at worst) with the fertility clinic, not with the authorities. The importance that a recipient attaches to donor information can be broken down into two categories - utilitarian and emotional. It is right to presume that recipients will ascribe utilitarian (pragmatic and medical) importance to donor information, which is (among other reasons) why it is right that rudimentary information is available from all donors. However, it is not right to presume that that recipients either will or will not ascribe emotional importance to donor information. Both attitudes should be accommodated, and the authorities should remain neutral in the matter. Since the entitlement to donor anonymity was removed, psychological concerns have also been raised about the donor themselves, specifically about their trepidation at the possible impact upon them and their family, if a child born as a result of their donation should contact them 18 years later. Additionally, all individuals conceived from a donor's gametes – whether via donation or as part of the donor's own family – have the option to contact one another (effectively, to locate their genetic half-siblings) via voluntary registers such as UK DonorLink or the Human Fertilisation and Embryology Authority's Donor Sibling Link resource. One concern that has been raised

concerning gamete donors is specific to egg donors who participate in egg sharing schemes. These schemes enable women to receive fertility treatment sooner and/or at reduced cost if they donate some of their eggs for use in the treatment of other fertility patients. Studies have indicated that in a scenario where a woman's fertility treatment is unsuccessful, and that woman has participated in an egg sharing scheme, she may feel anxiety at the thought that her biological child is being raised by others (see the journal article 'An assessment of the motives and morals of egg sharing donors: Policy of "payment" to donors requires a fair review', Kamal Ahuja et al, 'Human Reproduction', October 1998). Another type of human bodily material we wish to address here is umbilical cord blood stem cells. There is a tension between the optimum method of obtaining cord blood stem cells, and the aim of minimising health risks to mother and child. This tension is more pronounced in relation to private cord blood banking, where procuring the optimum number of cells is a more urgent priority than it is in public cord blood banking. In order to collect the optimum number of nucleated cells necessary for a cord blood transplant, it is recommended that the cord is clamped early and the cells collected whilst the placenta remains in utero. These practices involve potential health risks to mother and child, which should be clearly communicated to the pregnant woman before collection. There is also a risk to those who collect the cord blood stem cells – the risk of potential liability if anything goes wrong (see the journal article 'Tying the cord around the midwife's neck: the problem with umbilical cord blood collection', Karen Devine, 'Journal of Professional Negligence', 1 July 2010). For gamete donors, cord blood donors and other donors of human bodily material, the principal benefit of donation is altruism – satisfaction at having helping others to create a family or having contributed to biomedical research. Furthermore, although explicit remuneration for gamete donation is prohibited in the UK, egg sharing schemes are permitted. These give participants the opportunity to receive fertility treatment sooner and/or at reduced cost.

Question 6

Autologous donation (self-directed donation) is a trend that is especially prevalent in the USA. For example, increasing numbers of people are freezing gametes (sperm and eggs) for their own future use long before they actually consider parenthood. Autologous donation also occurs in relation to other types of human bodily material, such as umbilical cord blood. The benefit from autologous donation accrues (at first glance) only to the donor. There is consequently a tension between autologous donation and some of the concepts, such as altruism, reciprocity and solidarity, commonly used to promote donation to others (see Richard Titmuss' 1970 book 'The Gift Relationship: From Human Blood to Social Policy'). However, it does not automatically follow from this that autologous donation is undesirable or unethical. Autologous donation is entirely compatible with notions of autonomy (including reproductive autonomy), and it may have the wider benefit of reducing demand for donated human bodily material. A recent study from the Leeds Centre

for Reproductive Medicine, reported at the European Society for Human Reproduction and Embryology's annual conference in June 2010, indicated that a large number of female students would freeze their eggs. The researchers surveyed 98 medical students and 97 students of education and sports studies. The average age of the groups was 21. They gave the students general information about the procedure of egg freezing and the costs involved (£3000 per attempt), and then asked if the students would consider having such a procedure. 80% of the medical students hypothetically said yes, compared to 50% of the education and sports studies group. The students said they would undergo egg freezing to allow time to build a career, a relationship, or become financially stable. This points to the interesting fact that autologous gamete donation is not only being used not only in the face of foreseeable fertility problems, but also as a 'just in case' precautionary measure. This is part of a broader interest in the idea of 'future-proofing' one's fertility, against both pathological infertility and the natural decline in fertility that occurs over the course of one's life. While there is nothing intrinsically wrong with the ambition of future-proofing one's fertility, there is a risk that current techniques for so doing become subject to unrealistic expectations. There is no guarantee, with current biomedicine, that preserved gametes or embryos can be used to ensure a future pregnancy. So anyone who defers parenthood, in the expectation that preserved gametes or embryos can be used to insure against future infertility, risks profound disappointment if every future attempt at fertility treatment is unsuccessful. Current UK law has interesting consequences for autologous donation. Storage of gametes for 'social' (non-medical) reasons is limited to 10 years, and where fertility problems are foreseeable, this may be extended to 55 years. This is an entirely arbitrary time limit in both instances, and the rationale behind distinguishing between social and medical storage is far from evident. We have no ethical objection to indefinite storage, and we concede the need for some sort of limit only for practical reasons, because the logistics of indefinite gamete storage would be difficult if the practice became routine. We would prefer the time limit for social gamete storage to be extended to the time limit for medical gamete storage.

Question 9

We believe that the concept of 'dignity' requires a more nuanced consideration than is provided in the consultation document. A useful starting point might be to distinguish between 'dignity as empowerment' and 'dignity as constraint', following David Beyleveld and Roger Brownsword in their 2002 book 'Human Dignity in Bioethics and Biolaw'. 'Dignity as empowerment' is a value reinforced through the exercise of autonomy, while 'dignity as constraint' is a value reinforced through the exercise of state authority. This is a useful distinction, because it explains the paradox that the value of 'dignity' can be appropriated by the state and used to oppose the interests of nominally autonomous individuals. The concept of 'commodification' used in relation to the concept of 'dignity' in the consultation

document also requires more nuanced consideration. A useful starting point might be to distinguish between 'narrow' and 'wide' approaches to this concept, following Margaret Jane Radin in her 1987 journal article 'Market inalienability' ('Harvard Law Review', June 1987). A 'narrow' approach to commodification addresses the attachment of monetary value to something, or its entry into the commercial sphere. This is relevant when remuneration, advertising or competitiveness occur. A 'wide' approach to commodification addresses the marginalising of something's sanctity. This occurs when people (for example the donors of human bodily material) are viewed instrumentally, as a marginalised means to an end. It is also worth considering the extent to which the concepts of 'dignity' and 'commodification', as invoked in the formulation of policy, are predicated on either religious or secular views. Religious considerations should not play a strong role in the formulation of policy, because condemning practices based on religious views compels those who do not hold such views to abide by them. A more permissive approach is preferable, because provided that it allows scope for people (including those working in science and medicine) to act according to their conscience, such an approach allows those who disagree with practices to refrain from engaging in them.

Question 10

The most important of the values listed in the consultation document, and the one that should take precedence in most, if not all instances, is that of 'autonomy'. A logical corollary of making autonomy paramount is scope for commercial transactions involving human bodily material. Three of the other values listed in the consultation document – 'maximising health and welfare', 'reciprocity', and 'solidarity' – combine to form an important secondary consideration. This consideration is the fact that it is incumbent upon all of us who believe donation to be desirable (especially those of us who work in science and medicine) to persuade the public of the merits of donating human bodily material (or consenting to donate it after death). In other words, society should encourage, but not compel, its citizens to become donors.

Question 11

Altruism is an admirable quality. It is self-evidently more altruistic to donate human bodily material without any expectation of compensation than it is to donate human bodily material with an expectation of compensation. So in one sense, the answer to this question is a clear 'yes'. However, other considerations are also relevant here. The possibility of compensation may encourage sufficient numbers of additional donors to result in a net maximisation of health and welfare. And the maximisation of health and welfare is as important a moral consideration as altruism. The problem with the way this question is formulated, and the reason it is difficult to provide a straightforward answer, is that the question invites us to either accept or reject the counterposition of altruism to the pursuit of self-interest.

Perhaps a more useful distinction is that between vulgar self-interest and enlightened self-interest. Vulgar self-interest implies a tangible benefit (such as financial remuneration) accruing to the individual concerned. Enlightened self-interest, on the other hand, can involve benefits that are either tangible or intangible (a feeling of altruism being an example of the latter). And enlightened self-interest can involve benefits that accrue either to the individual, to the society they form a part of, or indeed to humanity as a whole. So the ultimate moral good involved in the donation of human bodily material derives from the pursuit of enlightened self-interest. And the pursuit of enlightened self-interest may or may not involve an expectation of compensation.

Question 12

The donation of human bodily material should be regarded as admirable, but not compulsory. The imposition of a duty to donate human bodily material would be onerous. Clearly situations may arise where the individual donates bodily material though a sense of 'moral duty'. What these situations are and when they occur depend upon the individual's concept of 'moral duty', their particular circumstances and the social mores of the time. Therefore the list of examples where such a duty may arise is fluid and as a result endless. There is a duty involved in the donation of human bodily material, but it is not the duty to donate. Rather, it is the duty of all of us who believe donation to be desirable (especially those of us who work in science and medicine) to persuade the public of the merits of donating human bodily material (or consenting to donate it after death). In other words, society should encourage, but not compel, its citizens to become donors. In recent years, the UK Government shelved plans to introduce an 'opt-out' system for organ donation, after experts cast doubt on whether the system would work. The rejected system would have allowed doctors to presume consent had been given to organ removal after death, unless objections had been made in advance (see the report 'The potential impact of an opt out system for organ donation in the UK: an independent report from the Organ Donation Taskforce', Department of Health, 17 November 2008).

Question 13

Participation in first-in-human trials should be regarded as admirable, but not compulsory. The imposition of a duty to participate in first-in-human trials would be onerous. There is a duty involved in participation in first-in-human trials, but it is not the duty to participate. Rather, it is the duty of all of us who believe participation to be desirable (especially those of us who work in science and medicine) to persuade the public of the merits of participating. In other words, society should encourage, but not compel, its citizens to participate in first-in-human trials.

Question 14

It is important to try to meet demand, because failure to do so makes it more likely that unregulated and potentially unsafe practices will prosper. For example, online sperm donation services which operate without a license from the Human Fertilisation and Embryology Authority often use fresh donated sperm, which has not gone through the standard clinical procedures of freezing and screening for disease or infection. Unlike those who donate sperm for use by licensed clinics, those who donate sperm for use by unlicensed services are considered under UK law to be the child's legal father, with all attendant rights and responsibilities. As to whether some 'needs' or 'demands' are more pressing than others, there have always been those who seek to disparage or deprioritise gamete (sperm, egg and embryo) donation on the grounds that the absence of pregnancy is not a disease. However, this reasoning is fallacious. Infertility is classified by the World Health Organisation not as a misfortune, but as 'a disease of the reproductive system defined by the failure to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse' ('The International Committee for Monitoring Assisted Reproductive Technology and the World Health Organisation revised glossary on assisted reproductive technology terminology', Fernando Zegers-Hochschild et al, 'Human Reproduction', 4 October 2009). That said, we would not go so far as to endorse the concept that there is a right to have a child. Article 8 of the European Convention on Human Rights describes a 'right to respect for...private and family life', and some have interpreted this as implying the existence of a right to have a child. But in our view, attempting to ensure that everyone who wishes to have a child can do so is a matter of pursuing a laudable aspiration and addressing the disease of infertility, not a matter of protecting or enforcing a right. An acute shortage of donor gametes is diminishing the capacity of the UK's public and private health sectors to treat infertility, resulting in growing concern and lengthening waiting lists at clinics. The shortage is widely attributed to the removal, in 2005, of entitlement to donor anonymity. There was initial optimism at the fact that the number of gamete donors actually rose slightly following the removal of anonymity, but this optimism was misplaced. The rising number of donors has been countervailed by a decreasing willingness on the part of donors to donate sperm to banks for use by multiple families. This has resulted in a worsening shortage overall – an increase in number of sperm donors, but a decrease in available donor sperm. We should strive to meet the needs of infertile people because prioritising the allocation of scarce gametes remains notoriously difficult, and questions of who is most deserving often arise. Currently, fertility clinics in both the public and private sectors have considerable latitude to implement their own criteria as to how gametes are allocated. This creates inequity, and a 'postcode lottery' of access to gametes. The criteria used to prioritise gamete recipients are at best contentious and a worst downright unfair. These include the age of the prospective recipients, whether or not they have a healthy lifestyle, and whether or not they are childless. Regarding the latter, debates about the definition of 'childlessness' abound – do deceased children, children from previous marriages, or the children of one's partner mean that one

should not be considered childless? What are the legal and regulatory parameters surrounding the allocation of gametes? The Human Fertilisation and Embryology Act 1990, as amended by the Human Fertilisation and Embryology Act 2008 states that 'a woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for supportive parenting)'. The most recent (eighth) edition of the Human Fertilisation and Embryology Authority's Code of Practice suggests that 'supportive parenting' should be interpreted as 'a commitment to the health, development and wellbeing of the child' and that 'it is presumed that all prospective parents will be supportive parents in the absence of any reasonable cause for concern that any child who may be born, or any other child, may be at risk of significant harm or neglect'. The same Code of Practice states that 'those seeking treatment are entitled to a fair assessment', and that 'patients should not be discriminated against on grounds of gender, race, disability, sexual orientation, religious belief or age'.

Question 15

Yes, there is scope for many different forms of incentive, compensation or recognition be used to encourage people to provide different forms of bodily material or to participate in a first-in-human trial, and this is to the good. We believe that autonomy is paramount, and a logical corollary of this is that there should scope for commercial transactions involving human bodily material, concerns about dignity and commodification notwithstanding. In the case of gametes and embryos, any action which promotes the donation of these materials by informed, autonomous adults is not to be discouraged. This is already the case with egg sharing schemes, which enable women to receive fertility treatment sooner and/or at reduced cost if they donate some of their eggs for use in the treatment of other fertility patients or for research. Explicit remuneration for gamete donation is prohibited in the UK, although 'loss of earnings' compensation to donors is permitted. The Human Fertilisation and Embryology Authority is currently reevaluating the sperm, egg and embryo donation policies that were developed as a result of an earlier policy review (see 'A report on the Human Fertilisation and Embryology Authority's review of sperm, egg and embryo donation in the United Kingdom', Human Fertilisation and Embryology Authority, 7 October 2005). Theoretically this reevaluation includes considering whether or not to permit explicit remuneration. But in practice, remuneration is precluded by European law, which specifies that 'member states shall endeavour to ensure voluntary and unpaid donations of tissues and cells', and that 'donors may receive compensation, which is strictly limited to making good the expenses and inconveniences related to the donation' ('Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells').

Question 16

The only form of 'incentive' that we would find intrinsically unethical would be one that was predicated on bad faith, imposed sanctions upon non-donors, or otherwise amounted to coercion. One example would be only allowing donors to become recipients. Another example would be withholding state-administered pensions or benefits from individuals who had chosen not to donate. It makes no ethical difference who offers an incentive to donate. Evidently, it is only meaningful to discuss the detail, consistency and regulation of 'official' incentives, as other incentives come under the auspices of people's private affairs.

Question 18

There is no significant distinction between indirect and financial compensation, and the insistence that there is such a distinction is misleading. Unfortunately, the disingenuous pretence that there is such a distinction is necessitated by the UK's compliance with European law, which specifies that 'member states shall endeavour to ensure voluntary and unpaid donations of tissues and cells', and that 'donors may receive compensation, which is strictly limited to making good the expenses and inconveniences related to the donation' ('Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells'). It is difficult to establish whether or not compensation is commensurate with 'the expenses and inconveniences related to the donation', not least because diverse individuals make donations in diverse circumstances (see our answer to Q19). Egg sharing is a means of nominally indirect compensation that has been permitted in the UK, but is open to criticism on the grounds that it is not significantly different from direct compensation. Direct compensation would be a more transparent and honest arrangement.

Question 19

Yes. Economic losses are more objective, and therefore more easily measurable, than subjective factors such as time, discomfort or inconvenience. However, this is not to say that it is impossible to ascribe a monetary value to discomfort and inconvenience and calculate a flat rate accordingly to different forms of gamete donation. Judges make such calculations every day, in personal injury claims. The introduction of payments for time, inconvenience and discomfort should be seriously considered. The most recent (eighth) edition of the Human Fertilisation and Embryology Authority's Code of Practice prohibits 'payment of a 'flat rate' to all donors (for example, £20 to all sperm donors)'. It also states that 'donors may be reimbursed all reasonable expenses incurred in the UK in connection with donating gametes or embryos (for example a standard-class rail ticket by the most direct route), but not excessive expenses if these would be benefits in themselves',

and that 'expenses claimed by donors should be directly linked to the process of donation (for example, the cost of travel to the centre, or the cost of childcare during donation when the donor would normally be caring for the child)'. The Code of Practice sets a maximum limit on compensation, stating that 'donors may be compensated for loss of earnings (wherever they live) up to a daily maximum of £61.28 but with an overall limit of £250 for each course or cycle of donation'. This figure is too low. The number of working days in the year (excluding annual leave and sick leave but including weekends and bank holidays) is 260, and if you multiply this by the daily maximum compensation of £61.28 for gamete donors, you get the figure of £15,932.80. The median weekly pay for full-time employees in the UK in April 2009 was £489, equating to £25,428 per annum or £97.80 per day ('2009 annual survey of hours and earnings', Office for National Statistics, 12 November 2009). In other words, if one takes as good coin the claim that payment for gamete donation amounts to 'loss of earnings' compensation, then the maximum payment allowed transpires to be woefully inadequate.

Question 20

It is hoped that advancements in stem cell technology and regenerative medicine will lead to the creation of gametes and organs in the laboratory. For example, researchers at Newcastle University have treated human embryonic stem cells with a chemical to prompt them into becoming germline stem cells – stem cells that are found in the reproductive organs, and give rise to eggs and sperm. By selecting out these germline stem cells and continuing to grow them in the presence of chemicals, they have been successfully developed into early-stage human sperm cells. If such techniques should lead to the successful creation of mature human sperm cells, and if it therefore becomes possible to create 'in vitro derived' gametes in the laboratory, then this would represent a considerable advance in our understanding of human development. Furthermore, it could also potentially allow babies to be created without the need for donated gametes. This could have useful therapeutic applications – for example, in those whose testes or ovaries have been affected or removed in the course of treatment for cancer. However, therapeutic use of in vitro derived gametes is currently prohibited in UK law. The Human Fertilisation and Embryology Act 1990, as amended by the Human Fertilisation and Embryology Act 2008, allows only 'permitted' eggs and sperm – defined as eggs and sperm that have been 'produced by or extracted from' the testes or ovaries – to be placed in a woman. It might be possible to reduce the demand for donated gametes through the use of in vitro derived gametes, and it is important that this research is pursued and that a change in legislation permitting its therapeutic application is considered. That said, the state of this research and its possible application has been somewhat exaggerated in media coverage – the challenges that still need to be overcome are considerable, and therapeutic applications may still be a long way off. We must take care not to create premature expectations or false hope.

Question 21

People should be assumed to be autonomous, rational agents capable of considering forms of encouragement and choosing to resist them. It is therefore unlikely that any form of encouragement would invalidate a person's consent, so long as this encouragement did not involve sanctions or coercion (see our answer to Q16). There are many areas of life in which encouragements and incentives exert an influence, and are not deemed to invalidate a competent individual's ability to consent. Rather, the individual is considered capable of weighing the costs and benefits of a course of action. The same principle should apply to the donation of human bodily material.

Question 22

'Coercion within the family' is not a meaningful or useful concept. Family members exercise and elicit dutiful actions in relation to one another as a matter of course. There is nothing wrong with this – indeed, in many respects it is a positive thing. If there is reason to suspect that a criminal act of coercion has taken place within a family, then the law is already equipped to address the matter. There is no need to be specifically concerned about coercion within the family, and certainly not in relation to human bodily material. One example that is commonly given, of the family supposedly posing a problem in relation to human bodily material, is that of 'saviour siblings' – children deliberately conceived in such a way that renewable tissue from their body (such as bone marrow) can be transplanted to a sibling afflicted with a severe disorder. The argument used is that because saviour siblings are conceived with an instrumental purpose in mind, their welfare has been compromised. The error in this argument is the assumption that an instrumental reason for conceiving a child defines or circumscribes the way that the parents subsequently relate to the child. Whatever the initial motivation for having a child (and there are many possible motivations), this does not detract from the fact that the child has and is cared for by loving parents.

Question 23

Yes, there are circumstances in which it is ethically acceptable to use human bodily material for additional purposes for which explicit consent was not given. As explained in our answer to Q2, stem cells are special inasmuch as they have greater potential than other cells in the body to differentiate into different types of cells. Stem cell lines are families of constantly dividing cells derived from an initial group of stem cells, and it would be prohibitively difficult to subject the uses of all cells in a stem cell line to the same standards of consent as applied to the original stem cells. The possible and desirable uses of stem cell lines are constantly changing as science develops, and cannot be foreseen in such a way as to obtain advance consent. Tracing stem cell donors to obtain explicit consent for new research stages may be disproportionately onerous. In the USA's case Moore v

Regents of University of California ([1990] 51 Cal. 3d 120; 271 Cal. Rptr.146), a patient with leukaemia alleged the commercial exploitation of his cell line, and argued that as the owner of the cells, his property right had been compromised by the work carried out on them. The court ruled that he had effectively abandoned the cells when he surrendered them to his physicians, and that it was inappropriate to recognise property in the body. Had the court ruled in favour of Moore, this would have effectively created a 'litigation lottery' for every researcher who works with cell samples, and would have impeded development in science and medicine. After evaluating the legal and ethical dimensions of the property proposal, the Nuffield Council on Bioethics recommended in its 1995 report 'Human Tissue: Ethical and Legal Issues' that human tissue should not be treated as a commodity, and that taking and using it should be managed through a framework of consent, with an immorality exclusion applied to patents in the area of human and animal tissue.

Question 24

Wherever possible, it should be the case that people make decisions for themselves. Where adults lack full capacity to make decisions for themselves, both the Mental Capacity Act 2005 and the Code of Practice issued by the Department for Constitutional Affairs to accompany the Act go into detail about how decision making can best be facilitated by others (see in particular Chapter 3 of the Code of Practice, 'How should people be helped to make their own decisions?'). In the case of children who must make a decision, a Gillick competence test is preferable to automatically assigning decision making power to parents (see the UK's case *Gillick v West Norfolk and Wisbech Area Health Authority* [1985] 3 All ER 402). However, where children have not attained Gillick competence, it is appropriate that their legal parents should make decisions on their behalf. By definition, no child consents to their own conception. This does not pose a problem, except in the case of 'saviour siblings' – children deliberately conceived in such a way that renewable tissue from their body (such as bone marrow) can be transplanted to a sibling afflicted with a severe disorder. Some have expressed concern that a child conceived with the express intention that they will donate bodily material to their sibling in this way cannot have consented to the arrangement. We believe saviour siblings to be a special case where the lack of consent does not pose a significant problem. As explained in our answer to Q22, we do not believe that their welfare has been compromised by the circumstances of their conception. That said, we think it is correct that saviour sibling arrangements are restricted to the donation of renewable tissue. The donation of non-renewable tissue, or of whole organs, is a far more problematic scenario that would indeed impact adversely upon the welfare of the child concerned. The main problem with saviour sibling arrangements as they stand is not that they are unethical, but that parents are precluded from accessing such an arrangement because Primary Care Trusts often incorrectly categorise saviour siblings within their fertility budget. This is because the creation of a

saviour sibling involves in vitro fertilisation, a process most commonly associated with fertility treatment. In this situation, however, it is not being used to address infertility. Nonetheless, parents wishing to conceive a saviour sibling are often unjustly subjected to the criteria that are used to ration fertility treatment, even though they are not infertile. If 'childlessness' is a prerequisite then the parents automatically fail to access this treatment on the NHS.

Question 25

Where a deceased person's wishes are known, their family has no legitimate part to play in deciding whether their bodily material may be used after death, and should certainly not have any right of veto. Where a deceased person's wishes are not known, their family – in consultation with medical staff – have a role to play in deciding whether their bodily material may be used. However, this latitude should not extend to procuring gametes for use in conceiving a child. The example of Diane Blood (in the UK's case *R v Human Fertilisation and Embryology Authority, ex parte Blood* [1997] 2 All ER 687) amounted to a dispute over whether consent had been obtained from the deceased for his sperm to be used in fertility treatment to be given to his widow. Since the court decided that consent had indeed been obtained, it was correct to conclude that his widow had license to use his sperm. The example of Keivan Cohen (in Israel's case *New Family Organisation v Committee for Approving Surrogacy Agreements Tel Aviv District Court 2007*) is more troubling, as it amounted to a dispute not only over whether the deceased wished to have children (it seems reasonable to conclude that he did), but also whether this gave his family license to use the sperm to impregnate a woman he had never met. The fact that the court ruled in the Cohen family's favour is regrettable, as the deceased had clearly not consented to his sperm being used by this woman in this way.

Question 27

We would have no objection to UK law permitting individuals to sell their gametes (sperm and eggs) and stem cells. We believe that autonomy is paramount, and a logical corollary of this is that there should be scope for commercial transactions involving human bodily material, concerns about dignity and commodification notwithstanding. Such an arrangement need not lead to exploitation. Indeed, in the case of gamete donation one could argue that a rigidly altruistic framework for donation is in some ways more exploitative, as the altruistic donor is the one person who receives little or nothing from the arrangement (while the recipient gains the gamete and the medical professionals are paid for their work). One could counter that the altruistic donor is recompensed for loss of earnings, but as explained in our answer to Q19, this 'loss of earnings' compensation compares poorly with the median pay received by full-time employees in the UK. The example of Jonathan Yearworth (in the UK's case *Yearworth and others v North Bristol NHS Trust* [2009] EWCA Civ 37) marks a court's willingness to regard gametes as

property for the purposes of a negligence claim. This is potentially the first step towards classifying gametes as property for the purposes of sale in the UK. People should be assumed to be autonomous, rational agents capable of weighing the costs and benefits of selling their bodily material.

Question 29

There are already conditions imposed upon the donation of gametes (sperm and eggs) that prevent sperm donors from creating hundreds of offspring. Donors may stipulate how many families they wish to help to create, with an upper limit of ten. This is an important and legitimate policy (although whether ten families is the correct upper limit is an open question), not least because the removal of donor anonymity means that any children born as a result of donation may identify and contact their donor once they are aged 18. If a gamete or embryo is donated for fertility treatment, the donor may wish to make the donation to a friend or family member, a situation called 'known donation'. The donor has 'control' over their donation, inasmuch as they can withdraw their consent at any point up to the implantation of the embryo. But the 'control' stops there – the donor is not recognised in law as having any parental relationship to a child born as a result of their donation. A small number of gamete donors wish to place conditions on their donation – for example, they may not wish their gametes to be used by a single woman, or a lesbian couple, or someone over a certain age. Such conditions pose a moral problem, because they introduce an element of bad faith into a system which is largely predicated upon good faith. Such conditions also pose a legal problem, because although they are not prohibited in the Human Fertilisation and Embryology Act 1990 or the Human Fertilisation and Embryology Act 2008, they will be prohibited by the Equality Act 2010 once its provisions come into force in October 2010. We think that just as the Human Tissue Act 2004 prohibits the placing of conditions upon the donation of tissue or organs, so the same principle should apply to the donation of gametes or embryos. For the reasons we explain in our answer to Q23, if gametes, embryos or stem cells are donated for research purposes, generic consent should be obtained in order to ensure that this research is not impeded.

Question 30

The inability to procure an adequate supply of donor gametes in the UK is encouraging patients to travel abroad for fertility treatment. In the first study of its kind in the UK, researchers from De Montfort University interviewed 51 people about their reasons for seeking fertility treatment overseas and their experiences of it. The study, led by Professor Lorraine Culley, found that 71 % of those interviewed went abroad to seek treatment using donor gametes. Overseas treatment may result in compromised care either overseas (where quality control and inspection procedures may not be in place) or back in the UK (where patients may struggle to gain access to follow-up care). Furthermore, overseas treatment

undermines domestic policy and regulation by allowing it to be circumvented – for example, in relation to identifiable donors, sex selection and single embryo transfer. The shortage of donor gametes in the UK poses problems not only for fertility treatment, but also for research. For example, somatic cell nuclear transfer, which aims to generate patient-specific stem cells to create replacement tissue, is dependent upon a sufficient supply of human eggs. The shortage of donor gametes in the UK is partially attributable to the lack of an adequately funded body with a sustained marketing strategy raising awareness of the problem. The National Gamete Donation Trust does excellent work, but is hamstrung because of its lack of infrastructure and limited budget (it has only one paid member of staff). If the model for gamete donation in the UK continues to be altruistic, as seems likely for the foreseeable future, then the donor recruitment strategy needs overhauling and sustained investment. That said, if the UK were able to move away from the altruistic model of gamete donation, then this would be a welcome development. Many countries, including the USA, buy and sell gametes routinely, and the Human Fertilisation and Embryology Authority has no jurisdiction to prevent Britons from travelling abroad to do so as well. A regulated market framework for gamete donation may ultimately be the best way to protect the interests of UK citizens.