

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.

CARE

## Give and take?

### Human bodies in medicine and research

Consultation Response to the Nuffield Council on Bioethics

From CARE

#### **About CARE**

CARE is a social policy charity with a Judeo-Christian foundation seeking to bring enlightened comment to public policy and practical care in society. We represent 60,000 individuals who share CARE's concerns with regard to myriad issues including human trafficking, bioethics gambling, poverty and education.

#### **Question 1**

**Are there any additional types of human bodily material that could raise ethical concerns?**

Hybrids and Chimeras: Much effort has been invested in research to produce various types of tissue with a view to repairing damaged organs and tissue, through stem cell research. We comment on the ethical issues raised by creating hybrids, cybrids and transgenic animals, using human material as stem cells sources below (Q 20).

Chimeras may be humans with one or two animal cells placed in them (or vice versa), or even a whole organ. Whether this raises ethical concerns or not depends partly on the type of cell or organ involved. Cells or organs that serve as mechanical functions are of less ethical concern, although they do generate safety and medical risks. Some of the issues arising from creating chimeras are similar to those generated by xenotransplantation, which is discussed further at Q20. However certain organs or tissue such as brain and germ-line cells are intimately associated with our humanity and, in the case of gametes, the nature and species of offspring, and thus generate ethical concerns about our humanness. The transfer of human brain cells to animals has already been undertaken into mouse fetuses by Wiseman at Stanford University, and is likely to progress further. This is both disturbing and degrading to humankind and generates concerns such as where do we stop? Is it all right to create a chimeric mouse whose brain tissue is 20% human or 70% human? Presumably any mouse that shows any human-like behaviour would have to be killed, which would generate further ethical concerns over the deliberate creation and then killing of a part-human creature. Whilst this may be far ahead in the future, we suggest that such proposals and research channels are better rejected before they are realised.

Cloned embryos and transfer of a human cell nucleus from one cell to another. The ethical concerns with the creation, use and destruction of cloned human embryos in order to generate stem cells are well known. Suffice to say, CARE strongly disagrees with the creation and destruction of cloned human embryos, believing it to be unnecessary (in view of progress with iP cells and other adult stem cell research), unsafe and unethical.

Fetal tissue is a further highly contentious body tissue that has been proposed for transplant use and therapies. The ethical issues raised are examined further in Q2. Since fetal tissue must be fresh and healthy, only products from procured abortions can realistically be used for transplant purposes. This raises issues about abortion, consent and whether it might encourage women to have a termination if they are unsure about the pregnancy or if they need transplant tissue for themselves or a relative.

## Question 2

### Should any particular type(s) of human bodily material be singled out as 'special' in some way?

2.1 Gametes: Gamete and embryo donation generate different ethical issues and should be treated differently. Embryos are nascent human lives, deserving of protection from conception, and can (and should, where possible) be adopted,<sup>1</sup> whereas gametes are not living human beings but should be treated differently to other human tissue because of their unique and special status as determinants of genetic identity for future children. However both embryo and, particularly, gamete donation unavoidably raise issues of significance to the children born that must be acknowledged. The genetic relationship is bound up in fundamental aspects of human living - conception, birth, sex, procreation, death and generational replacement. There is real significance in the power of biological connection. The importance, and long-term impact on people, of this personal genetic heritage cannot be underestimated. Knowledge of genetic ancestry is of medical and scientific importance, both for genetic research and for the care of people with genetically-related medical conditions. For many people, though not all, knowledge of ancestry and personal history is of value in itself and it forms part of their conception of their own identity. For them, parenthood is a link in a chain of genetic connections that reaches back into the past and forward into the future. They are entitled not to be deprived of this knowledge, even if others regard such concerns as negligible.

*"My experience is that genetic identity and genetic relationships have a very deep, very special, almost magical part to play in the psychological health of human beings."* Whereas, in contrast, deliberately denying children this information can lead to *"...rootlessness, identity problems, future difficulties with their social parents and problems in attaining adulthood."*<sup>2</sup>

In a recent survey 65% of donor offspring agreed that: *"My sperm donor is half of who I am."* 45% agreed that: *"The circumstances of my conception bother me."*<sup>3</sup> Almost half reported that they think about donor conception at least a few times a week or more often. 36% still have concerns about donor conception even if parents tell the truth about it. And a noticeable minority (11%) say that donor conception is hard for the kids even if the parents handle it well. Thus about half of donor offspring (47%) have concerns about or serious objections to donor conception itself, even when parents tell their children the truth. See Q4.3 below.

The use of eggs for research purposes is likely to be of concern for many people because: *there is probably a **majority of people** (for whom) the deliberate discarding of human embryos is morally troubling*.<sup>4</sup> Indeed, for most Christians the creation and then killing of human embryos is morally unacceptable.

2.2 Embryos: The embryo is a living human, a member of the human species. Human embryos under the current law have a right to special treatment and respect. They are not treated in the same way as other body material because of their unique status. The embryo's future claims need protection, because of its capacity to mature into a rights-bearing individual. The idea of protecting future claims before their owner can assert them is well established in both law and ethics. For example, a child's inheritance can be protected and a child can apply for compensation for injury at fetal stage. This means they should not be treated as simple raw material for research and destruction.

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<sup>1</sup> There is a successful embryo adoption service in the US called Snowflakes.

<sup>2</sup> Rupert Rushbrooke, Journal of Fertility Counselling, Vol.6, no.1, 1999.

<sup>3</sup> Marquardt, Glenn, Clark. 2010. *"My Daddy's Name is Donor: A New Study of Young Adults Conceived Through Sperm Donation."* Institute for American Values. This study uses an unprecedented, large sample. It also directly compared the experience of donor conceived persons with that of people who were not donor conceived – both those who were adopted and those who were raised by their biological parents. The study employs a representative sample drawn from over one million households. "The empirical data itself, however, is rich and deserves the attention of prospective parents, policy makers, researchers and bioethicists. It is unique insofar as it contains the largest reported sample to date and its methodology successfully prevents selection bias to the extent possible. Furthermore, it is the first study of this scale which provides comparisons with adoptees and with individuals who were raised by biological parents". Professor Vardit Ravitsky BioNews 563, June 2010.

<sup>4</sup> Sheila McLean, *New approach could ease the stem-cell fears*, The Scotsman, 25/08/06.

2.3 As noted above, embryo stem cells, cloned embryos and cybrids all require 'special' treatment due to the nature of their creation and 'human' status. See our comments at Q20.

2.4 Fetal material: The use of body tissue from a fetus requires special consideration, due to the material source. The use of tissue from spontaneous abortions is ethically acceptable. However this is not a practical option because in spontaneous miscarriages the fetus often dies some time prior to expulsion, so the tissues will not be viable. There is also a higher incidence of chromosomal and genetic abnormalities, especially those in early pregnancy.

However the use of tissues or stem cells from aborted fetuses is highly controversial, because of its association with elective abortion. Many people have strong moral objections to using tissues or stem cells obtained from aborted fetal tissue. The end use does not justify the means for obtaining the material. A 1995 survey by the Joint Centre for Bioethics at the University of Toronto found that, among women who would consider having an abortion, 17% would be more likely to undergo an abortion if fetal tissue could be donated for medical use. This indicates that fetal transplantation would be used, at least in part, to justify an abortion. Moreover, it could be argued that the transplantation doctor using fetal tissue is an integral part of the abortion process because s/he would have to be close to the theatre where the abortion was taking place in order to receive the tissue virtually immediately.

2.5 Umbilical cord blood. CARE considers that cord blood is a special, useful (and ethical) source of stem cells for storage for therapies or transplant in the future. There is a need to raise awareness of its potential and encourage more publicly funded and supported cord blood storage and banks.

### Question 3

#### **Are there significant differences between providing human bodily material during life and after death?**

There are significant differences between provision of body parts during life and after death. We detail a number of these.

3.1 Organ donation. Some of the general ethical issues regarding organ donation are explored in more detail in the following question. We comment here on the significant differences – and the ethical issues raised - between organ donation by a live person and a dead person.

3.2 Dead donors. Firstly, a unique concern with organ donation after death, compared to before death, is with the **ascertaining and timing of a diagnosis of death**. The blurring of distinctions between life and death is aggravated by organ donation. Some experts suggest that a way of increasing the supply of deceased-donor organs can be done by redefining the criteria by which people are declared dead, for example, Selton argues that it is reasonable to broaden eligibility by redefining death. (However she does acknowledge that there is little reason to believe that adding these donors will significantly reduce the shortage.)<sup>5</sup> Truog says that: *"the medical profession has been gerrymandering the definition of death to carefully conform with conditions that are most favorable for transplantation."*<sup>6</sup> The kinds of dilemmas raised are whether 'death' should reference the brain or other organs? How long must the heart have stopped beating before a patient is unambiguously, irreversibly, dead? How can a specific time be put on something that is, in essence, a process?<sup>7</sup> CARE holds deep concerns about introducing shorter observation times, and with the potential retrieval of organs before death, because two to five minutes of cardiac arrest is not always sufficient for a heart to be 'dead'. Truog claims that everyone agrees that many patients could be resuscitated after an interval of 2 to 5 minutes, however they are not, because of

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<sup>5</sup> Selton, S. 2008. *When Altruism isn't Enough*. Washington: The AEI Press. P5.

<sup>6</sup> Truog, R. & Miller, F. 2008. "The Dead Donor Rule and Organ Transplantation". *The New England Journal of Medicine*. Vol.359 (7), pp. 674-675.

<sup>7</sup> There is no standard imposed delay in the US between cessation of cardio-respiratory function and the harvesting of organs. It seems it can be anything from ten minutes to being discounted altogether (Mason and Laurie 2006: 501). Most US hospital policies follow the recommendations of the Institute of Medicine: waiting at least five minutes with no heartbeat and no meaningful cardiac electrical activity. In the UK 10 minutes is standard practice.

a prior choice not to reverse.<sup>8</sup>

Moreover, treatment before death may be influenced by the preservation of organs after death. If initiating organ procurement is being considered before death is pronounced, procurement may begin before the patient is *unambiguously* or irreversibly dead, leaving questions as to whether decisions will be influenced by the doctor's desire to preserve organs rather than allowing patients to die as humanely as possible. Clearly it is of great concern if events surrounding death are ever manipulated to accommodate organ retrieval.

Secondly, whilst the human body after death does not justify the same level of respect or treatment as a living human there is, nevertheless, **a certain level of respect required** of the human body after death. In situations of organ donation after death, respect for the dead means not treating their bodies as mere raw material or simply as a potential source of spare parts.

Thirdly, the issue of **consent** also exposes differences between donation in life and death. Whilst CARE supports the principle of organ donation, it is important to remember that it is donation. It is a gift, freely given (not sold) and should not be coerced or presumed. For this, and many other reasons, CARE does not support presumed consent upon death. An Organ Donation Taskforce likewise has concluded that organ donation should be encouraged, but presumed consent should not be introduced.<sup>9</sup> CARE welcomes and supports this position (see our more detailed comments on 'presumed consent' or 'opt-out' at Q12).

In 2008 the President's Council on Bioethics studied in detail the issues around the definition of death and transplantation. One of its primary conclusions was that: "*the central ethical challenge for any transplantation protocol is to give the gift of life to one human being without taking life away from another*."<sup>10</sup> (our emphasis). In other words, we must care equally for the prospective donor and recipient, whilst maintaining the intrinsic value of vulnerable human life, the gift element of donation and awareness of the danger in re-defining death.

3.3 Live organ donation. Provided the functional integrity, as opposed to bodily integrity, of the donor remains intact, an organ such as a kidney can ethically be donated to save another if the donor has given his/her free, full and informed consent.

**Consent** is clearly an important issue for live donation as well as after death. Before death, living organ donors, according to the World Medical Association (WMA), have a right to information about 'the benefits and risks of transplantation' and in particular about 'the implications of living without a donated organ'. This means donors should not just be given information but should be given the opportunity to ask questions and have them answered sensitively and intelligibly (WMA 2006, para 20). In addition, special efforts should be made to ensure the choice about donation is free of coercion. There should be no more or less subtle pressures in the form of financial incentives. In most countries, including the UK, payment for organs is illegal and should remain so. The WMA would like the payment of donors to be prohibited everywhere since payment encourages people to take unwarranted risks with their own health (WMA 2006, para 23) while also undermining the principle of unbiased, coercion-free consent. See also further comments on this Q4 and Q20.

3.4 Gamete donation before and after death also raises issues regarding **consent**. As noted above, the use of donated gametes to create another human or to use for research is ethically controversial, involving the use of personal genetic data. Because of its sensitive nature, and the long-term consequences on offspring, donation should not be undertaken lightly or without full, free, informed consent, both before and after death. Consent for use after death should be in writing.

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<sup>8</sup> Truog, R. & Miller, F. 2008. "The Dead Donor Rule and Organ Transplantation". *The New England Journal of Medicine*. Vol.359 (7), pp. 674-675.

<sup>9</sup> Organ Donation Taskforce. 2008. The Potential Impact Of An Opt Out System For Organ Donation In The UK: An Independent Report From The Organ Donation Taskforce. P 34.

<sup>10</sup> The President's Council on Bioethics. 2008. *Controversies in the Determination of Death*. A White Paper of the President's Council on Bioethics. Washington DC. p119.

#### Question 4

**What do you consider the costs, risks or benefits (to the individual concerned, their relatives or others close to them) of providing bodily material? Please distinguish between different kinds of bodily material if appropriate.**

##### 4.1 Organ Donation

There is a shortage and thus demand for organs for donation, particularly ones that are fresh and healthy.

However organ donation raises issues about bodily integrity. Before death, in neither ancient nor modern understandings is self-harm praised as a virtue. The question of bodily integrity is paramount in regard to live organ donors and live organ donation can violate bodily integrity. It is contrary to the Hippocratic (and indeed Beauchamp and Childress) principles of 'do no harm'. The removal of a kidney from a live donor does not contribute to his/her health. However, it can be argued that the removal of an organ for the sake of saving another can be justified, since it is possible for the body to remain functional with one kidney only. CARE would suggest that whilst special caution is needed for permanently injuring a healthy person, for the sake of the health of another it can generally be regarded as morally licit provided it does not greatly disadvantage the donor. The advantage to the recipient must always outweigh the disadvantage to the donor and, of course, a strong emphasis must be put on informed consent.

It is increasingly becoming accepted practice to use donors with an established emotional or biological link to the recipients. This not only benefits the recipient but the altruistic act involved in donation can be a benefit to the donor as well as recipient, especially if there is a biological link.

We note again that a major source of organs is from the newly dead, which raises questions of when to define death (see Q3.2). There is a real risk that ventilators may be turned off too early, or not even turned off, until liver, heart and/or lungs are removed, because they need to be perfused with blood). Some clinicians question whether donors on ventilators really are dead and whether it is appropriate to rely on the concept of 'brain death', especially if someone is breathing and their heart is beating. The risks of dead donor donation are explored above in more detail.

##### 4.2 Umbilical Cord Blood and adult stem cells

There are benefits in collection and storage of umbilical cord blood for both donor and recipient. The donor may not receive direct benefits (unless the donor is able to use the stored blood in the future for therapies) but potential indirect benefits from research carried out using the donated blood, or perhaps indirect benefits from treatment for a family member. This is particularly so if the donor has a rarer blood group or disorder that would benefit from further research.

The potential costs and risks to consider include the storage of personal genetic data in the public domain, and the research use of these stem cells and cord blood. How much control - if any - does the donor have over its use in different types of research? Is there adequate data protection of personal data? Can anonymity of personal data be ensured? Does the donor have any rights over his/her personal genetic data? Can consent to use be amended or rescinded at any time?

4.3 Gamete donation generates a number of benefits, costs and risks to donors and recipients. Moreover a third party is also affected, the child born of donated gametes. Indeed, the child is the one party who has no choice in the matter but who is the one most directly affected by the decision. It is probably fair to assume that there are benefits for the adult *recipients* of donated gametes and presumably altruistic benefits for donors. It could also be argued that it is better for children born of donated gametes to have life, to exist, than to not exist (a philosophical debate that is explored by Almond 2006). However, as noted above, there are significant ethical (and some practical) costs born by the resulting offspring who will have no biological connection with their social parent(s) and may never know about their complete genetic heritage.

From the parents – recipients - perspective, the use of donated gamete(s) will unbalance the parental role and relationship, because the child will be the biological child of one parent, and a stranger. Thus

research has found that a commissioning (non-genetic) father is significantly more reticent than a commissioning (genetic) mother of informing the child of its biological origins.<sup>11</sup> Donation can involve secrecy and presumably lies. Research work by Golombok on the psychological impact of IVF and DI treatment on children and parents found that most parents do *not* tell their DI child about the method of conception, and *do not intend to* in the future.<sup>12</sup> A European study by Golombok found that by the time donor children reached 11-12 years old, only 8.6% of parents had told their children about their conception procedure.<sup>13</sup>

Denying children fundamental knowledge of themselves can adversely affect the child's development of a secure identity (and thus welfare), with consequences throughout their adult lives. Golombok's work is usually cited to show there are few negative outcomes for such children however her research uses very small samples and is mostly pre-teen, yet it "...*is at adolescence that issues of identity become salient for children and it is also at adolescence that difficulties in parent-child relationships are most likely to occur.*"<sup>14</sup>

Other research has found that, once told, over 80% of offspring are likely to pursue identity and contact with donors and many hope for more than simply knowing their donors' identities. Furthermore, over 60% wanted to learn more about and possibly meet the donor's family.<sup>15</sup>

Anecdotal perspectives provide another slant to the 'costs' involved in donation. "*I have communicated directly with, or read opinions by, many offspring of reproductive technology. Without exception, they all express a desire to know their biological origins. Any study of human culture will tell you the importance of kinship.*" (Barry Stevens, aged 47).<sup>16</sup>

There are similar findings in the recent report *My Daddy is a Donor*<sup>17</sup> (see reference 2 above) that found more than half of donor offspring (53%, compared to 29% of the adopted adults) agree that: "*It hurts when I hear other people talk about their genealogical background.*" Donor offspring are significantly more likely than those raised by their biological parents to struggle with serious, negative outcomes such as delinquency, substance abuse, and depression, even when controlling for socio-economic and other factors. More than one-third of donor offspring born to lesbian couples in the study agree it is wrong deliberately to conceive a fatherless child.

Moreover, when young people today discover that they are conceived with a sperm donor, sooner or later they begin to struggle with the dawning awareness that they might well have a half-dozen, or a dozen, or scores, or hundreds, of *half-siblings* – all over the place

Adoption is a good, vital, and positive institution that finds parents for children who need families. Although we cannot draw exact parallels with adoption for donation, this does not mean that we cannot draw any conclusions at all from the lessons of adoption. If anything, the similarities between the struggles that adopted people and donor conceived people might share should prompt caution about intentionally denying children the possibility of growing up with their biological father or mother, as happens in donor conception.

It is also going to be increasingly likely that donor information will need to be updated and/or amended with any new genetic knowledge about the donor's health that would be of interest or importance to the offspring. At the moment DI children are unable to contribute their full family medical history and health at

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<sup>11</sup> Brewaeys, A., Golombok, S., Naaktgeboren, N., de Bruyn, J.K., Van Hall, E.V., Dutch parent's opinion about confidentiality and donor anonymity and the emotional adjustment of their children, *Human Reproduction*, Vol.12, No.7, (1997).

<sup>12</sup> For example, *Follow-up studies on the psychological consequences of successful IVF treatment*, Golombok et al, *Biomedical Ethics*, vol. 3, 1998.

<sup>13</sup> Golombok et al, *The European Study of Assisted Reproduction Families: The transition to adolescence*, *Human Reproduction*, Vol. 17(3): 840-40 (2002).

<sup>14</sup> *Surrogacy: Review for Health Ministers of Current Arrangements for Payments and Regulation*, HMSO, 1998.

<sup>15</sup> *Adolescents with open-identity sperm donors: report from 12-17 year olds*, Scheib, Riordan & Rubin, *Human Reproduction*, 2004.

<sup>16</sup> *Speaking For Ourselves*, Quotes from Men and Women created by DI Conception.

<sup>17</sup> Marquardt, Glenn, Clark. 2010. "*My Daddy's Name is Donor. A New Study of Young Adults Conceived Through Sperm Donation.*" Institute for American Values.

medical check-ups. This will only be exacerbated as society becomes aware of more disorders that have a genetic basis (e.g. breast cancer or glaucoma). Children and parents will request - and need - information on their genetic heritage in order take appropriate precautions for their future health (e.g. regular check-ups and/or dietary or lifestyle changes).

Egg donation generates significant medical costs and risks to the donors of eggs, which we explore in more detail at Q6.

#### Question 5

**What do you consider the costs, risks or benefits (to the individual concerned, their relatives, or others close to them) of participating in a first-in-human clinical trial?**

#### Question 6

**Are there any additional purposes for which human bodily material may be provided that raise ethical concerns for the person providing the material?**

6.1 CARE has major reservations about the use of egg donation and sharing. Egg donation is unpleasant and risky, it puts vulnerable (financially and emotionally) women at risk and creates a greater likelihood of exploitation. Egg sharing and reducing IVF fees is a deliberate inducement for women to donate eggs and can therefore be regarded, in effect, as a 'benefit in kind' or even 'financial gain', in the same way as direct monetary 'payments' would be. Most women do not choose voluntarily to 'give' eggs away, as evidenced by this offering of cut-price treatment.

Contrary to commonly held assumptions by the public; the procedures and drugs used to extract eggs have **not** been adequately studied. Indeed, it is of very real concern to us that data has not been collected. Suzanne Parisian, a former Chief Medical Officer of the US Food and Drug Administration, has stated that: "*Pharmaceutical firms have not been required by either the government or physicians to collect safety data for IVF drugs regarding risk of cancer or other serious health conditions despite the drugs having been available in the United States for several decades.*"<sup>18</sup>

The lack of investigation and analysis of drugs used for egg extraction means that women contemplating any form of egg donation are not being provided with the information necessary for making a fully informed choice.

The American Society of Reproductive Medicine (ASRM) says that mild forms of OHSS actually occur in **10–20% of cycles**, significantly more than the HFEA has claimed.<sup>19</sup> This figure means that between 1 in 5 to 1 in 10 of all treatment cycles could result in OHSS. OHSS has been associated with death and has been reported in women with polycystic ovaries, in younger women, and in women with high estrogen hormone levels and after a woman receives either GnRH agonist or hCG. OHSS carries an increased risk of clotting disorders, kidney damage, and ovarian twisting. Ovarian stimulation in general has been associated with serious life threatening pulmonary conditions in FDA trials including thromboembolic events, pulmonary embolism, pulmonary infarction, cerebral vascular accident (stroke) and arterial occlusion with loss of a limb and death.<sup>20</sup> Indeed, as of June 2005 five women in the UK were known to have died of OHSS.<sup>21</sup>

While such events seem to be relatively rare, it is possible that other deaths and other longer-term side effects of ovarian hyperstimulation have simply not been linked officially to the egg extraction procedures that preceded them. For example, Dr. Suzanne Parisian states that:

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<sup>18</sup> Parisian S. Open Letter, February 2005. <http://handsoffourovaries.com/pdfs/appendixb.doc>

<sup>19</sup> *Egg harvesting for stem cell research: medical risks and ethical problems*, RBM Online, Beeson, D., & Lippman, A., 14/8/06.

<sup>20</sup> Beeson, D., Testimony to Congressional Hearings House Government Reform Subcommittee on Criminal Justice, Drug Policy and Human Resources - Hearing on Stem Cell Research, March 7, 2006.

<sup>21</sup> BBC News, 2005, From: *Egg harvesting for stem cell research: medical risks and ethical problems*, RBM Online, Beeson, D., & Lippman, A., 14/8/06.

*“Studies to date have not ruled out a possible link between stimulation drugs and increased risk of ovarian cancer.”<sup>22</sup>*

In the absence of long-term follow-up it is impossible to assess accurately the seriousness of the long-term risks to women’s health from either the expanding use of egg extraction, or the potential effect on women’s reproductive health in the future.

Another of the worrying medical consequences of ovarian hyperstimulation for women may be serious abnormality in their future children. This is of course only a risk and, again, not one that is fully verifiable unless more data is collected. Nevertheless, women need to be informed of all such potential risks, in order to be able to make fully informed, unbiased decisions.

There is also the danger that to stimulate enough eggs to be able to ‘share’ some, women may be given extra dosage of drugs. There have been calls for regulation of the drugs used in IVF treatment because some clinics are exceeding recommended levels: *“This is the only area of medicine where drug dosages are not regulated, and that’s wrong. We have recommended doses but they are not binding and some clinics are exceeding these levels.”<sup>23</sup>*

6.2 Donation of cells or eggs for hybrid research, mitochondrial research etc. Many potential donors, as well as the broader public, wrongly believe that therapies are likely to result from embryo research in the near future, so they believe that providing eggs is a way to help others around them. In fact therapies from embryonic stem cells research are still far off, have yet to be seen and may never result. Embryo cloning has also been described as *‘a wildly inefficient process, requiring hundreds of eggs from perhaps thousands of women to merely attempt to produce a single viable clone’.*<sup>24</sup>

Women need to be clearly informed if their eggs will be used for cloning or embryonic stem cell research; to create cloned embryos that will then be destroyed when they reach 14 days old. As already noted, this use of eggs is likely to be of concern for many women because there is probably a majority of people for whom the deliberate discarding of human embryos is morally troubling.<sup>25</sup>

6.3 PGD and Tissue Typing. The creation of so-called ‘saviour siblings’ through pre-implantation tissue-typing suggests only cord blood donation will result. However insufficient attention has been paid to the future welfare of the children themselves as potential donors of *bone marrow and other tissue*. We suggest that children born following pre-implantation tissue-typing need, and should be given, **special and explicit protection** against this. One possibility would be to set a limit to the use that could be made of them, so that they would not be subjected to an indefinite number of medical interventions. For example, regulations could specify that they should not be subjected to more than two rounds of bone marrow transplantation and that they should not be used to harvest organs. Admittedly, this could give them more protection than would be offered to a naturally conceived child who was later found to be a suitable tissue-match for a relative, but firstly, this is a separate issue that might itself merit legislative consideration in some other context, and secondly, limitation in these circumstances could be considered a necessary acceptance of responsibility for the child’s situation in view of the potential for exploitation of that child.

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<sup>22</sup> Parisian S. Open Letter, February 2005. Also *Uterine Cancer after Use of Clomiphene Citrate to Induce Ovulation*, Althuis M.D., Moghissi K.S., Westhoff C.L., Scoccia B., Lamb E.J., Lubin J.H., and Brinton L.A., *American Journal of Epidemiology*, April 1, 2005; 161(7): 607-615.

<sup>23</sup> *Why leading fertility expert thinks women are being put at risk*, Independent, 8/10/06.

<sup>24</sup> *Mining the secrets of the egg*, Dennis C 2006, 652–655. *Nature* 439.

<sup>25</sup> Sheila McLean, *New approach could ease the stem-cell fears*, The Scotsman, 25/08/06.

### Question 7

**Would you be willing to provide bodily material for some purposes but not for others? How would you prioritise purposes? (should any purposes be singled out for any form of special treatment or priority?)**

As made clear above, there is a need to distinguish between different types of bodily material. Most people will wish to prioritise and retain some element of control over the purpose to which their bodily material is put. Even with the least ethically controversial bodily material, as they do at the moment, people may wish to opt out of donating certain body parts – for instance, eyes are an issue for some – while being content that others are used. As medicine advances, people will wish to be increasingly specific about the organs or tissues they will donate; they might refuse their face for a face transplant, for instance.

### Question 8

**Would your willingness to participate in a first-in-human trial be affected by the purpose of the medicine being tested? How would you prioritise purposes? (should any purposes be singled out for any form of special treatment or priority?)**

### Question 9

**Are there any other values you think should be taken into consideration?**

While there are strong arguments now for personal freedom and the individual right to decide on research, donation and treatment, which we respect and value, we also note that we all live in community, not isolation, and the health, welfare and interests of other human beings therefore deserves the highest regard and protection from those around – from their community. So, for example, ‘children of choice’ have a right to at least one ‘choice’ of their own – that is a right to choose *knowledge* of their parentage and not to be deliberately deceived and deprived of it. A commitment to freedom of choice should recognise not just those of adults but also responsibility to the welfare and rights of those unable to choose.

We believe that the sanctity of human life must be taken into consideration.

Consent to use of bodily material is another consideration.

Nonmaleficence, (‘do no harm’) is important when considering donation of bodily materials.

The values of responsibility and personal conscience are both significant.

We also note the concerns with commodification and instrumentalism, reflected in the potential (and sometimes real) trading in human parts, such as through the sale or trade in organs, eggs and tissue.

### Question 10

**How should these values be prioritised, or balanced against each other? Is there one value that should always take precedence over the others?**

Different people will have different value systems and world views, which make consensus in determining the most important values almost impossible. However various statutory instruments can help in determining some priorities, as there will be some level of agreement.

So, the UNESCO Universal Declaration on Bioethics and Human Rights,<sup>26</sup> Article 3 on human dignity states that: “*The interests and welfare of the individual should have priority over the sole interest of science or society.*” Thus, practically, ensuring the welfare and complete protection of women and offspring should be accorded the greatest priority, over the interests of scientific research. The Declaration of Helsinki similarly states that: “*The interests of the subject must always prevail over the interests of science and society.*”<sup>27</sup>

The Charter of Fundamental Rights of the European Union: Article 3 (Right to the integrity of the person): states that in the fields of medicine and biology, the following must be respected in particular “the prohibition on making the human body and its parts as such a source of financial gain,”

The EU [Directive 2004/23/EC 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](#) lays down the necessity for free and informed consent of donors of human tissues and cells (including gametes) whether for transplantation or research purposes. It also encourages Member States to ensure that all donations are voluntary and unpaid to prevent parts of the human body becoming the subject of trade.

Art 2(b) of the European Convention for the Protection of Human Rights and Fundamental Freedoms 1950, as set out in the Human Rights Act 1998, states that everyone’s right to life shall be protected by law, thus emphasising the sanctity of human life.

#### Question 11

**Do you think that it is in any way better, morally speaking, to provide human bodily material or volunteer for a first-in-human trial for free, rather than for some form of compensation? Does the type or purpose of bodily material or medicine being tested make a difference?**

#### Question 12

**Can there be a moral duty to provide human bodily material, either during life or after death? If so, could you give examples of when such a duty might arise?**

We do not consider that there is a moral duty to donate bodily material, it should remain as a gift. Indeed, Meilaender asks: “*In what sense is there a shortage of organs that must be overcome?*” (2006). Donation of organs is not therapeutic for donors; they are given for utilitarian reasons for someone else’s benefit, which is why Meilaender also questions if it is right to “*aim at my own harm in order to do good to my neighbour?*” (1996: 93)<sup>28</sup> or should it be regarded as an unreciprocal gift? We agree with Pope John Paul II who has called donation “*a decision of great ethical value*”, a noble gesture and a “*genuine act of love*” (2000: 1).

We reiterate again our concern here that the UK does not introduce presumed consent (an opt-out system). There is no moral duty to donate organs and we should not lose sight of the altruistic notion that organ donation is just that. It is a gift, freely given (not sold) and should not be coerced or presumed. Importantly, the concept of a gift freely given is an important one to both donor families **and to transplant recipients**. The Organ Donation Taskforce concluded that an opt out system of consent has the potential to undermine this concept.<sup>29</sup>

Research by the Organ Donation Task Force found support from members of the public and patients’ groups for the principle of informed consent, and a perception that assuming consent from silence

<sup>26</sup> United Nations Educational, Scientific and Cultural Organization, Organisation des Nations Unies pour l’éducation, la science et la culture, 24<sup>th</sup> June 2005.

[http://portal.unesco.org/shs/en/file\\_download.php/11445d5a75d2306d7437f0626f35e1c1Draft\\_EN.pdf](http://portal.unesco.org/shs/en/file_download.php/11445d5a75d2306d7437f0626f35e1c1Draft_EN.pdf)

<sup>27</sup> Declaration of Helsinki, as revised in 1983.

<sup>28</sup> As opposed to aiming at my neighbour’s good, knowing that in doing so I may be harmed (Meilaender 2006: 93).

<sup>29</sup> Organ Donation Taskforce. 2008. The Potential Impact Of An Opt Out System For Organ Donation In The UK: An Independent Report From The Organ Donation Taskforce, p17.

belongs to a more paternalistic era. Some felt that an opt out system could be ‘dehumanising’. A move away from requiring explicit consent would put organ donation out of step with prevailing practices and would be inconsistent with the Human Tissue Authority’s guidance on consent. It would also challenge commonplace assumptions about consent and individual decision making at a time of greater expectation of individual autonomy among the public. Given that current trends in healthcare place great emphasis on choice and responsiveness, this is an important consideration. There are also concerns about the potential for provoking anti-donation feelings and even active anti-donation campaigning.

Many people interviewed for the Task Force had concerns that their best interests might be jeopardised if they were seen to be potential organ donors. The fear that you might not actually be dead, with doctors ‘jumping in too quickly’ before ‘someone is definitely gone’, was one that was widely expressed (p17).

Further arguments for and against presumed consent were explored by the task force and we generally agree with their conclusions.<sup>30</sup> We appreciate the desire to increase donation so have made suggestions on improving donation rates at Q15 below.

Lastly, we note that for some donor offspring, their deep discomfort about their origins appears to lie, at least in part, in their feeling of being a product made to suit their parents’ wishes – of being made, not born. “*If my life is for other people’s purposes, and not my own, then what is the purpose of my life?*”<sup>31</sup>

### **Question 13**

**Can there be a moral duty to participate in first-in-human trials? If so, could you give examples of when such a duty might arise?**

### **Question 14**

**Is it right always to try to meet demand? Are some ‘needs’ or ‘demands’ more pressing than others?**

There will always be other demands, both urgent and trivial. However ‘good’ ends do not justify all means of obtaining them. It is unethical to justify over-riding the interest of others or of society for the sake of the benefits accrued. Humans must never become mere properties, objects or instruments of use, regardless of the end purpose. “*That people should treat others as means to their own ends, however desirable the consequences, must always be liable to moral objections.*” (Warnock Committee Report 8.17). Thus the emphasis should not be on ‘demand’ or the ‘ends’ but on the donor and the donation process, ie altruism, free and informed consent, and consideration of the welfare of donors as well as the children born of donation.

### **Question 15**

**Should 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?**

15.1 We are aware of the arguments for compensating donors as well as proposals to ‘encourage’ donation through ‘opt-out’ or ‘presumed consent’. For example, Satel has recently argued for compensation for donors and describes in detail how a feasible compensation-based system could be designed, including revision of US law.<sup>32</sup> She suggests offering incentives such as health insurance, tax credits, tuition vouchers, or a contribution to a tax- free retirement account to individuals willing to donate a kidney to a stranger. She claims that people who donate should receive some material reward for their generosity. However CARE strongly disagrees with this, for the reasons detailed following.

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<sup>30</sup> Organ Donation Taskforce. 2008. The Potential Impact Of An Opt Out System For Organ Donation In The UK: An Independent Report From The Organ Donation Taskforce.

<sup>31</sup> Marquardt, Glenn, Clark. 2010. “*My Daddy’s Name is Donor: A New Study of Young Adults Conceived Through Sperm Donation.*” Institute for American Values, p31.

<sup>32</sup> Satel, S. 2008. *When Altruism isn’t Enough*. Washington: The AEI Press.

15.2 CARE considers that any form of compensation for inconvenience or risk to donors should not be permitted because it will inevitably act as an incentive for some people to donate organs, tissues or gametes, particularly the financially or emotionally vulnerable. There should be no hint of any buying and selling in human lives or body parts, nor anything that could construe 'payment'. Providing benefits in kind would effectively be an inducement to donate body materials, in the same way as direct monetary 'payments' would be. The WHO observes that a trade in body organs commodifies the body and is often accompanied by exploitation. Unfortunately, however, there are frequent reports about living donors of transplanted kidneys, or eggs, who are remunerated directly or indirectly in many countries (WHO 2003, para 11).

EU regulations make it clear that member countries should not consider both direct and indirect inducement, as the following paragraphs<sup>33</sup> state: *The human body and its parts shall not, as such, **give rise to financial gain or comparable advantage**. The aforementioned provision shall not prevent payments that do not constitute a financial gain or a comparable advantage, in particular:*

- *Compensation of living donors for **loss of earnings and any other justifiable expenses** caused by the removal or by the related medical examinations;*
- *Payment of a justifiable fee for legitimate medical or related technical services rendered in connection with transplantation;*

The Explanatory Report of the Additional Protocol on transplantation of organs and tissues of human origin says that Article 21 should be interpreted as follows:

*113. It states in particular that the human body and its parts must not, as such, give rise to financial gain or comparable advantage. Under this provision, organs and tissues should not be bought or sold or give rise to direct financial gain for the person from whom they have been removed for a third party. Nor should the person from whom they have been removed, or a third party, **gain any other advantage whatsoever comparable to a financial gain such as benefits in kind** or promotion for example. A third party involved in the transplant process such as a health professional or a tissue bank may not make a profit from organs or tissues or any products developed from them.*

15.3 Regarding egg 'donation' through egg sharing and reduced IVF fees; the provision of such a direct financial incentive is a *deliberate inducement* for women to donate eggs and can therefore be regarded as a 'benefit in kind' or even 'financial gain', in the same way as direct monetary 'payments' would be. Without such inducements, women rarely agree to voluntarily undertake the inconvenience, pain and risk involved in egg donation as the costs clearly outweigh the benefits.

Undoubtedly, compensation creates a financial incentive for economically vulnerable women to expose themselves to both known and unknown health risks for money. As an EP resolution states: *"despite the possibility of serious effects on women's life and health, the high price paid for egg cells incites and encourages donation, given the relative poverty of the donors."*<sup>34</sup>

Offering a significant amount of money off IVF fees *will* compromise a woman's decision on whether to donate eggs or not, especially if she is economically disadvantaged in any way. An egg 'sharing' arrangement cannot be construed as donating 'surplus' eggs because the few eggs that a woman does not use in an initial IVF cycle would generally be frozen for her future use, should she either want more children or should the initial treatment fail.

Thus CARE believes that reducing IVF fees falls into the category of perceived financial inducement to donate and should not be permitted. Despite attempts by scientists and the HFEA to price eggs through paying for treatment, they are not commodities to be priced, and nor are women's lives. Almond (2006: 117) states that there is a general judgement that the sale of human eggs, sperm or embryos is contrary to human dignity. It evokes distant echoes of the sale of human beings in slavery.

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<sup>33</sup> Council of Europe - Explanatory Report of the Additional Protocol on transplantation of organs and tissues of human origin, for Article 21.

<sup>34</sup> European Parliament resolution on the trade in human egg cells, 10 March 2005.

15.4 Children born of sperm donation: The role of money in their conception disturbs a substantial number of donor offspring. 45% agree: *"It bothers me that money was exchanged in order to conceive me."* 42% of donor offspring, compared to 24% from adoptive families and 21% raised by biological parents, agree that: *"It is wrong for people to provide their sperm or eggs for a fee to others who wish to have children."*

Instead, we believe that gamete donation should be altruistic and that the whole process should be carried out for the long-term benefit of the child. It is important that the child knows that his/her parent did not 'sell' their gametes for any sort of payment. The quotes above illustrate the damage that can be done to a child who realises that they were created mainly for money.

A practical concern to record is that when any kind of payment is involved for donors, they may be tempted to withhold information that, if known, would make him or her unsuitable as gamete donors.

15.5 Alternative incentives to increase donation. There are alternative options to increase organ and tissue donation, not involving monetary compensation or presumed consent. We note the following conclusion of the Organ Donation Task Force: *"The Taskforce believes that there are simpler and easier ways of substantially increasing the numbers of organs available for donation, without the complexity and difficulties of trying to implement an opt out system."* Moreover, it adds: *"...most compelling of all, we found no convincing evidence that it would deliver significant increases in the number of donated organs."*<sup>35</sup>

Perhaps most importantly, there is a need to increase awareness of donation: *"Awareness of the organ donation registration system is low in the UK. Many people were aware of donor cards but few knew where to obtain them. Only a minority were aware of the Organ donor Register (ODR)."* Barriers to donation include lack of awareness, laziness, unwillingness to think about death, a lack of trust in medical professionals and concerns about how donors are treated. However these are surmountable within the current legal system and importantly, willingness to donate is high.

*"(There is a) need to address the extremely low awareness of the ODR. If a person's name is on this register, 90% of families consent to donation, compared with a general consent rate of about 60%. There is a clear need to publicise the register and to make the process of registering easier and more widely understood. Other areas for development include the following:*

- *many people have fears or misgivings about organ donation based on misconceptions or 'myths' that need to be dispelled.*
- *We need to encourage people to talk about organ donation with their families and friends, as recommended in the draft NHS constitution."*

The opportunity to do good through donating organs could be more appropriately promoted within a system that gave people the means to positively opt in than through one that invited them to opt out if they wished to do so.<sup>36</sup>

Also feedback from work with faith leaders to the Task force suggested that faith-specific donor cards might be particularly helpful and would serve a dual purpose, since such cards would also remove doubts about whether a particular faith supports donation or not.

Registration should also be made easier and more visible and GPs could raise donation as a matter of course with their patients. Perhaps schools should also be involved in the education process.

15.6 As noted above, we are concerned about introducing presumed consent for many reasons. An additional concern is that if an opt-out or presumed consent system were introduced, the complexities

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<sup>35</sup> Organ Donation Taskforce. 2008. The Potential Impact Of An Opt Out System For Organ Donation In The UK: An Independent Report From The Organ Donation Taskforce. p23, 34.

<sup>36</sup> Organ Donation Taskforce. 2008. The Potential Impact Of An Opt Out System For Organ Donation In The UK: An Independent Report From The Organ Donation Taskforce. P5 + 15.

would be high, as would the costs, which were estimated at over £50 million by the Task Force.<sup>37</sup>

The Taskforce suggests that successful implementation of their recommendations (to improve awareness but *not* by introducing an opt-out system) could deliver a 50% increase in organ donor numbers within five years.

#### **Question 16**

**Are there forms of incentive that are unethical in themselves, even if they are effective? Does it make any difference if the incentive is offered by family or friends, rather than on an 'official' basis?**

It will be clear from our comments above that we do not support the concept of incentivising donation, but prefer instead encouraging, promoting and supporting it. Incentivising through family or friends would be an additional pressure that would be harder to resist.

Demand for 'raw material' has, not surprisingly, led to suggestions of introducing financial, or other, incentives. However donation means a gift, without compensation, with no strings attached. As already noted, a special moral objection has long been attached to the sale of human body material, including genetic, and a number of declarations by international bodies have explicitly ruled out commerce in human embryos and body parts (see Q15.2).

Fetal tissue raises specific issues about consent and incentives. While maternal consent to the use of fetal tissue may be obtained, the mother's situation may be too stressful for her to feel able to properly consider and reflect on whether she should allow her aborted fetus to be used as a tissue donor. In other words, women are particularly vulnerable at this time and therefore are less able to make rational decisions, and are more easily 'exploited' or persuaded. Moreover, the practice of fetal donation might encourage some women to have a termination in order to provide transplant tissue for a sick relative or even themselves.

Offering a reduction in IVF fees will certainly compromise a woman's decision on whether to donate eggs for treatment and/or research, or not, particularly if she is economically disadvantaged or emotionally vulnerable in any way. The process of egg donation and ovarian hyperstimulation is painful, invasive, dangerous and rarely necessary. It does not benefit the donor. It should never be undertaken for any type of financial inducement. Sharing eggs with a family member may be undertaken purely altruistically but should not be incentivised in any way.

#### **Question 17**

**Is there any kind of incentive that would make you less likely to agree to provide material or participate in a trial? Why?<sup>3</sup>**

#### **Question 18**

**Is there a difference between indirect compensation (such as free treatment or funeral expenses) and direct financial compensation?**

See our comments at Q15.2, Q15.3 and Q15.4.

#### **Question 19**

**Is there a difference between compensation for economic losses (such as travelling expenses and actual lost earnings) and compensation/payment for other factors such as time, discomfort or inconvenience?**

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<sup>37</sup> Ibid p21.

There is a difference, and the former is marginally easier to verify objectively. The latter is arbitrary and begins to undermine the concept of an altruistic gift. Ideally, CARE would prefer that no payments were made, even for compensation for actual losses and expenses. Donation should be a gift. As the EU directive noted earlier states: "*Member States shall endeavour to ensure voluntary and unpaid donations of tissues and cells*."<sup>38</sup> This would be the best way to ensure that all body tissue/organ donations are as altruistic as is possible and would avoid any arbitrariness in setting levels of expenses.

With regard to potential embryo donation, no payment for expenses or inconvenience, or any other benefits, should be provided to those who give up for adoption any surplus embryos created in the course of treatment. It is inappropriate for payments to be made for lives. It would be preferable for embryos to be given (free) for adoption, instead of being destroyed or researched on, as the successful US Snowflake adoption service does.

With regard to payment for expenses for gamete donors, the issue is raised again as to whether gamete donation should be purely altruistic, done for the benefit of the **child**, or should it be for the benefit of the **donor**? The EU directives make it clear that any financial inducement should not be considered by member countries and CARE strongly believes that compensation for inconvenience to donors should never be permitted because it will inevitably act as an incentive for some people to donate gametes (indeed, we assume this is would be the purpose of such a proposal). There should be no hint of any buying and selling in human body parts, lives, nor anything that could construe payment of sperm and egg donors. On the contrary, we believe that gamete donation should be altruistic and that the whole process should be carried out for the long-term benefit of the child. It is essential that the child knows that his/her parent did not 'sell' their gametes for any sort of payment (see Q15.4).

Another concern CARE holds (again as per Q 15.4) is that when any kind of payment is involved for donors, they may be tempted to withhold information that, if known, would make him/her unsuitable as donors.

However, we acknowledge that the reality is that some level of financial loss is likely to be incurred with gamete donation, and therefore the two EU directives permit only the reimbursement of necessary and verifiable expenses and loss of earnings. No compensation (nor indeed expenses) should be given to a donor if he or she could perceive this compensation as a financial incentive to donate. Moreover, it is difficult, and inherently arbitrary, to try to set an appropriate level of expenses, and any level that were to be set would have to be constantly revised. There should certainly be an upper limit, for the reasons stated above, but clearly some people will incur more expenses than other (travelling further, varying loss of earnings etc) which adds to the difficulty in setting expenses.

Hence CARE believes that it would be best to prohibit all expenses but, at the very least, to ensure only actual, verifiable, expenses incurred are reimbursed.

## Question 20

**Are you aware of any developments (scientific or policy) which may replace or significantly reduce the current demand for any particular form of bodily material or for first-in-human volunteers? How effective do you think they will be?**

20.1 The creation of IPS cells (induced pluripotent embryonic-like stem cells) involves neither the creation of embryos nor the use of human eggs, thus rendering them non controversial and potentially very beneficial in research and therapy. They should eventually compensate for the shortage of human eggs and avoid the need to create and/or research on embryos.

20.2 A way of meeting the shortage of human organs would be to use animal organs, xenotransplantation. To date there have been no successful cases of animal to human organ donation

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<sup>38</sup> The 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: Article 12, para 1.

however research is ongoing, particularly with using pigs. While rejection of organs is a major problem when transplanting across species, there is apparently some progress between pigs and baboons. However there is a very long way to go before it is possible to consider transplanting organs from animals into humans. Moreover, even if the rejection problem were resolved, there would remain other health concerns, particularly the risk of transmitting infectious diseases from animals to humans, including those that are harmless in animals but which could cause diseases in humans. These might then spread to the wider population. This is a real concern for public safety.

There are further concerns with the integrity of our humanity as a species and to the integrity of the human body as human. Some organs are particularly associated with our humanity, such as the brain, which is the centre for human self-consciousness and intellect. Thus while a brain transplant is unimaginable, even the transfer of limited number of brain cells from humans to animals or vice versa – which is imaginable – is highly questionable. This also applies to gametes, which are unique and essential to our dignity as humans, and determine the nature and species identity of our offspring too. However the recipient of a pig heart, liver or kidney would remain as human as the rest of us since these organs are purely functional, not specifically related to our humanity

Lastly, there are issues around animal welfare that should be considered. Animal rights groups have raised objections to animal-human transplantation, because of the pain inflicted on animals used in transplant experiments.

20.3 It has been proposed that the shortage of eggs might also be bypassed by using animal eggs to create animal-human hybrid embryos in order to obtain stem cells for research. The mixing of human and animal gametes should not be permitted, it is unethical, unnecessary<sup>39</sup> and scientifically dubious. We strongly disagree with the willful creation and destruction of compromised human beings (even up to the 14 day embryo stage) in order to provide manipulable raw materials. There are also major ethical concerns with crossing a rubicon and mixing animal and human genes. Even definitions become complicated, highlighting the disturbing nature of this type of research – currently cybrids would be defined as human, and they are indeed more human than not, however perhaps they would be better described as severely compromised human embryos (even sub-human embryos?), as they do contain some animal genes. This would create humans that are less than human.

20.4 The use of transgenic animals for pharmaceutical purposes is widespread. However it raises questions about where we draw lines in this research. There are safety issues if too many single foreign genes are transferred to the genome of an organism. The transfer of human chromosomes to animals raises a number of problematic ethical issues (for example human chromosomes have been transplanted to mice embryos which were then passed onto offspring). While this does not make the animals human-like, at what point will it? How far do we go? Should it be at 50/50 animal/human, or less or more? What significance would be given to nuclear DNA compared to mitochondrial DNA? On what basis would limits be set? (it appears arbitrary), Which species does the entity belong to? What legal protection would it have – human or animal? What are the time limits for research? (there is different protection for research on animals and human fetuses).

#### **Question 21**

**In your opinion are there any forms of encouragement or incentive to provide bodily material or participate in first-in-human research that could invalidate a person's consent?**

#### **Question 22**

**How can coercion within the family be distinguished from the voluntary acceptance of some form of duty to help another family member?**

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<sup>39</sup> There is one exception to this, which is the 'hamster test' to test male fertility. However this is no longer used because of the development of ICSI.

### Question 23

**Are there circumstances in which it is ethically acceptable to use human bodily material for additional purposes for which explicit consent was not given?**

No. This question raises again the issue of presumed consent for donation of organs, explored in more detail at Q12 above. With the current opt in system in the UK, the consequence of not registering wishes is that the potential pool of donors is decreased, but it is not personally harmful. However if the law were changed to an opt out (presumed consent) system, not registering may mean that someone's organs are taken when they had serious objections to this happening. If there was any evidence or suggestion that the deceased did not wish to be a donor, even though they had not recorded this decision on a register there would be a significant risk of successful legal challenge. Moreover, un-donated, it is more likely that the biological material would increasingly be treated as an impersonal commodity that could be accessed on tap, with all that this would mean for the way in which our culture would view the human body which could not but impact our culture's approach to the value of human life and human identity with potentially profound and unhelpful implications.

### Question 24

**Is there a difference between making a decision on behalf of yourself and making a decision on behalf of somebody else: for example for your child, or for an adult who lacks the capacity to make the decision for themselves?**

There is clearly a difference, and greater caution is needed in the case of incapacitated or vulnerable patients. The human dignity and wellbeing of the donor must always be a prime concern, hence the UNESCO 2005 guidelines which state that: *'the welfare of the individual should take priority over that of science and society.'* (Art 3.2).

24.1 It is widely accepted that children and incompetent adults should not normally be used as organ donors. The WMA states that: *"individuals who are incapable of making informed decisions, for example minors or mentally incompetent persons, should not be considered as potential living donors except in extraordinary circumstances."* (WMA 2006, para 23).

In the case of incapacitated adults and minors, the informed consent of legal guardians must be obtained and the subjects own wishes should be given serious consideration and respected where possible. Moreover, such people should not be subjected to any medical studies or research if these can equally well be undertaken on competent adults. Presumed consent is not adequate enough unless it is of benefit to the person.

In the UK an exception is when an organ such as a kidney is to be removed from a person under 18 if special permission has been granted by the Human Tissue Authority or a Court, as well as the legal parents. It is standard practice to obtain a child's own consent too, unless too young to be consulted. However CARE considers that it is morally dubious to use children as organ donors, since the removal of an organ is not advantageous to the donor. The donation of bone marrow, a regenerative tissue, is also problematic since it is both risky and painful and rarely beneficial to the donor. Donation of blood however is different as it is regenerative, not risky, and causes minor pain only.

24.2 The role of so-called 'saviour siblings' and their whole purpose in being created is relevant here. As we highlight at Q6 insufficient attention has been paid to the future welfare of the children themselves as potential 'donors' of bone marrow and other tissue ('donor' is an inaccurate term here, bearing in mind the inability of the child to provide informed consent and willingly 'donate'). We suggest that children born following pre-implantation tissue-typing need, and should be given, special and explicit protection against this. It would in our view be preferable that 'saviour siblings' were not created as their primary purpose in being is to provide body tissue (initially, and usually only, cord blood) for a sick sibling.

Our position echoes Kant's principle that people should not be used as a means to an end. Humans must never be treated as mere means for the sake of medical progress or for the good of science instead the interest of the individual must always take precedence.

We suggest that with such a sensitive and potentially ethically problematic issue, independent scientific and ethical scrutiny is needed, whose prime responsibility is to protect the rights, safety and wellbeing of human subjects.

#### **Question 25**

**What part should family members play in deciding whether bodily material may be used after death (a) where the deceased person's wishes are known and (b) where they are unknown? Should family members have any right of veto?**

#### **Question 26**

**To whom, if anyone, should a dead body or its parts belong?**

#### **Question 27**

**Should the laws in the UK permit a person to sell their bodily material for all or any purposes?**

No. See our comments at Q15. The State's general obligation is to protect its citizens from harm or abuse, especially the most vulnerable, and UK laws should reflect this.

#### **Question 28**

**Should companies who benefit commercially from others' willingness to donate human bodily material or volunteer in a trial share the proceeds of those gains in any way? If so, how?**

#### **Question 29**

**What degree of control should a person providing bodily material (either during life or after death) have over its future use? If your answer would depend on the nature or purpose of the bodily material, please say so and explain why.**

29.1 Organ donation: After death, the opting-out and opting-in consent systems vary considerably. In the UK relatives can give consent on behalf of a deceased person if no prior indication has been given by the deceased.

However not everyone will be willing to donate organs after death and we are concerned that the State should not be able to claim the right to use any body that falls into its hands in the name of 'presumed consent'. We are also concerned that if there is presumed consent, then 'donation' and 'gift' and 'altruism' cannot be assumed. Of course, it is possible under an opt-out system to attempt to ensure that proper information is given out but there remains a fear that advantage may be taken of ignorance by not providing proper information to the public about the right to opt out. Thus we strongly recommend retaining the opt-in system currently in operation in the UK.

As we say at Q7, there is a need to distinguish between different types of bodily material. Most people will wish to prioritise and retain some element of control over the purpose to which their bodily material is put in the present and future. Even with the least ethically controversial bodily material, as they do at the moment, people may wish to opt out of donating certain body parts – for instance, eyes are an issue for some – while being content that others are used. As medicine advances, people will wish to be increasingly specific about the organs or tissues they will donate; they might refuse their face for a face transplant, for instance.

See also our comments at Q23 and Q6.2.

29.2 Cell and tissue donation. Ethically sensitive issues such as donation of cells to create embryos for research, cybrids, etc clearly need to be treated separately, as we have made clear in our response to earlier questions.

**Question 30**

**Are there any other issues that you would like to draw to our attention?**