Church of England - Mission and Public Affairs Council

Question 1

While an individual's genome is strictly speaking 'information' rather than 'material', this information can only come from the donation of cells for genomic research and ought to be within the remit of this consultation. Hair donation for the creation of wigs has an ethical implication in that real-hair wigs are not available through NHS funding which covers a single synthetic wig only for recipients of chemotherapy, etc. There are two issues to be investigated here: is it ethical to advocate donation for private patients alone and can it be said that informed consent has been given unless donors are made fully aware that donated hair will not be made available to NHS patients?

Question 2

Material that may be used for reproductive purposes is different from other material since there is genetic transmission between a donor and any ensuing offspring. It is not sufficient to suggest that this is a 'merely biological' link since many physical and other personal traits are transmitted genetically. There is also the possibility of a social/personal link being established between donor and offspring, once a child is 18 years old. Issues of identity and personal history are often important for children born from certain assisted reproductive techniques and these ought not to be minimised. A distinction may also be drawn between gametes donated for gamete research and gametes that may be donated for embryo research since the creation of an embryo in vitro raises ethical issues that gamete research does not. Embryo donation is different from other forms of donation in that donors are not directly donating parts of their own bodies but rather they are donating a separate living entity that has had its origin from their gametes. Neural material donated directly or via stem cell production and subsequently transplanted either into an adult animal or an animal embryo/fetus may have the capacity to alter that animal's cognitive function in such a way as to give rise to 'near-person' status. This, clearly, has ethical, social and practical implications different from many other forms of transplantation Material donated by children or others lacking capacity, where parental or other third party consent is a determining factor, raises ethical issues with regard to the wellbeing and interests of the donor, not present in direct-consent donation.

Question 3

A number of significant differences may be identified: (i) Risks to the health and wellbeing of the donor in 'live donation' (LD); (ii) The possibility of relationships between donors and recipients being changed in unforeseen ways in LD; (iii) The decision-making process in LD might involve the donor alone, but after-death donation (ADD) often involves multiple family members with resulting implications

for family relationships; (iv)LD cannot, by definition, involve the whole body; donation of the whole body in ADD can have an adverse effect on family members who are 'left with nothing' during the bereavement process

Question 4
Benefits: (i) enhanced self-esteem as a consequence of altruistic behaviour (LD); (ii) positive sense of contributing to others' wellbeing which may express an individual's philosophy of life (LD and, prospectively, for ADD); (iii) small financial benefit, at present, for some forms of donation which often comes in the form of expenses but which leaves the donor with a small net financial gain (eg. hair donation, sperm and ova donation) Costs: (i) 'emotional cost' to families in whole body donation (ii) economic costs of travel/time off work etc, unless compensated for Risks: (i)health and well being risks associated with any surgical intervention, however minor or routine (blood, partial or whole organ and ova donation) (ii) unforeseen emotional and psychological risks associated with embryo donation (iii) unforeseen personal and social risks associated with gamete donation if any resulting child seeks information of genetic parenthood (iv) unforeseen usage of genome information if used in research or practice morally objectionable to the donor

Question 5
Costs: (i) travel/time off work etc unless compensation is offered Risks: (i) risks to physical health (ii): risks to psychological and social health if illness or incapacity result from the clinical trial (iii) risk to psychological wellbeing from the process of undergoing what others may present as a 'guinea-pig' experience Benefits: (i) increased self-esteem from acting altruistically (ii) sense of achievement if the clinical trial results in effective treatment being developed.

Question 6
(i) material donated for genome mapping (ii)material donated for human-animal chimera research

Question 7
It is reasonable to prioritise life-saving donations above other forms of donation because of their immediacy and effect. The end-effect of life-prolonging donations, however, is similar to that of life-saving donations although immediacy is not usually a factor. Some life enhancing donations may, at times, deserve equal priority to some life-prolonging donations: the impact on a young person, for example, of having his or her sight restored might be as significant as the impact of a kidney transplant on an elderly person whose life-expectancy may not be greatly increased by being enabled to live without dialysis. Life-creating donations, similarly, may have such a significant impact on people struggling with the effects of infertility that it is difficult to uphold a hard and fast sequence of priority for donations. Nonetheless, a general approach in which life-saving treatment is

prioritised over life-prolonging treatment which in turn is prioritised over life-enhancing treatment is a useful starting point for further discussion and application. Prioritising types of donations in this way may, for example, help to indicate how much time and which resources ought to be allocated to various donor campaigns. There are, however, further difficulties associated with attempts to prioritise donations. Many individuals are drawn to certain types of donation because of their interests, relationships and personal histories. Someone, for example, who may wish to donate ova may do so because infertility may be a particular areas of interest or concern to them. This person may not be prepared to donate a kidney or other body organs for transplantation even though others may view life-prolonging treatment as being more important than life-creating procedures. Similarly, while many may believe that enabling a person to have his or her sight restored is more important than enabling a person undergoing chemotherapy to have a better self-image by wearing a real-hair wig, it may be difficult to establish in many people's minds a link between their willingness to donate hair and a willingness to donate their corneas after death. By prioritising types of donation according to purpose, the end-result may be that fewer life-enhancing or life-creating donations will be forthcoming without a resultant significant increase in life-prolonging donations. Donating for research purposes is unlikely to attract quite the same interest or appeal as donations that are presented as life-prolonging, life-enhancing or life-creating and yet research projects may result in improved treatments at all levels. Prioritising types of donations runs the risk of limiting donations for research. There is also a difficulty in assessing the overall impact and relative importance that various forms of donation will have on their recipients. Donated gametes, for example, may totally transform, for the good, a couple's life and the lives of their extended family while a liver transplant may enable an individual to develop his or her gifts and talents not only for personal benefit but also for the benefit of society. Conversely, gamete donation may lead to a miserable family life or even child abuse and a liver transplant may see the recipient go on to continued alcohol or drug abuse. Trying to prioritise types of donation is fraught with such problems and difficulties. On the whole, apart from life-saving donations it may be better to try to encourage donation across the spectrum rather than to target specific types of donation. It is also probable that a number of people will draw a distinction between donating for members of their families and donating for ‘general’ purposes. Some individuals will also object to donating gametes or embryos for moral or religious reasons.

Question 8

For the reasons outlined in answer to Question 7, it is difficult to suggest a hard and fast prioritising of purposes for first-in-human trials. In addition, some individuals will not wish to take part in trials where the medicine or treatment being tested may be used in some forms of infertility treatment, post-coital contraception or abortion. Equally, some trials for medicines or treatment intended to address

sexual dysfunction may involve procedures that some may find objectionable.

Question 9

(i) The 'Right to Life'/affirmation of life: the Human Rights Act and the European Convention on Human Rights both advance the right to life as the foundation on which all other rights, responsibilities and duties are built. As such, the government and its agents have a responsibility to respect, to protect and to promote this right. In non-legal terminology the value of 'affirming life' forms the backdrop against which a discussion on donation is properly conducted. (ii) Care/protection of the vulnerable: care and protection of the vulnerable are among the hallmarks of a civilised society. There are vulnerable people both among potential donors and among potential recipients and their care and protection ought to be priority concerns.

Question 10

The right to life/affirming life ought to take precedence over other considerations as other values and principles are underwritten by this principle and set in context by it. Autonomy, for example, can only be properly exercised if one's right to life is secured. Similarly, the values of dignity, justice and maximising health and wellbeing will ring hollow unless the right to life is secured. The government's responsibility to respect, to protect and to promote the right to life does, of course, have its limitations. No one ought to be coerced by the government or its agents into undergoing personal risk, for example, even in the interests of another person's right to life. It is appropriate, however, for the government and its agents to encourage others to act in support of the right to life and to make some actions mandatory. In the ongoing debate on whether the UK ought to adopt an 'opt-out' policy with regard to organ donation, the Church of England supports a continuation of the current opt-in policy with active encouragement by government and its agents for individuals to choose donation. In this way the responsibility to promote the right to life is upheld but people are not pressured into making decisions that would compromise a correct exercise of personal autonomy. Caring for the vulnerable ought to take precedence over the other values outlined in the background information to Question 10 as this principle ensures that vulnerable people's rights (including the right to life) are protected and that they are enabled to exercise the other rights, privileges, responsibilities and duties that contribute to a recognition of their individual dignity and to their roles within society. The remaining values must be balanced against one another in the light of the discussion above. Within the context of encouraging the creation and maintenance of a cohesive and caring society, the exercise of individual freedom ought to be safeguarded, ensuring that any consent given for particular procedures or practices is valid, being both free and informed.

Question 11

It is unclear what is meant, in this question, by the term 'compensation'. If

compensation covers reimbursement of expenses, such as travel expenses or loss of earnings then such compensation does not constitute 'payment'. If compensation includes funding for time, 'goods' (donated material) or services (first-in-human trial)then, in effect, payment has taken place. It is not reasonable to ask donors to be out of pocket, so accepting reimbursement of expenses ought to be viewed as offering time, goods and services for free. This is preferable to donors being paid over and above expenses as it encourages positive values such as altruism, solidarity and a principled exercise of autonomy. Payment may compromise the exercise of genuine autonomy since some individuals may make decisions against their better judgement because of financial pressures. Payment may also lessen a sense of solidarity, replacing it with personal interest and it undermines altruism. While we accept payment for time, goods and services in many areas of life these do not involve permanently 'giving away' our bodies or parts of them as is the case in donation. The risk of 'commodifying' human bodies in this way carries with it further risks of undermining human dignity and compromising personal and social relationships. First-in-human trials do not involve permanent donation but they do involve temporary 'surrender' of our bodies to others for purposes that are not directly beneficial to us. While an ethically acceptable case may readily be made for individuals acting in such a way if they are acting out of altruism or solidarity, it is difficult to argue that it is ethical to act in such a way for financial gain. While an individual may have a right to act in such a way it does not follow that it is right to induce individuals to act in this way. Payment for participation in first-in-human trials is, therefore, questionable and if it is to occur at all, it ought to be correlated to potential loss of earnings (as outlined in the answer to Question 19) and not to be promoted as a means of financial gain. The considerations above apply to all forms of donation and first-in-human trials.

Question 12

It may be argued that everyone has a moral duty to act to save or to protect life if in so doing no unreasonable risk is incurred. (An example of an unreasonable risk would be a statistically significant probability of death or major injury following a particular surgical intervention. An example of taking a reasonable risk would be accepting that, as a true anomaly, death or significant injury might ensue or that, more frequently, a minor and transient injury may result.) There is, for example, a moral duty for individuals to donate blood in an emergency incident where to fail to do so might result in others' deaths. Since such occasions are relatively rare and since there is no requirement for all adults in the UK to donate blood or any other bodily material in order to save life, it is acceptable that, as at present, this is left to individual choice. If voluntary donations were to fall below the levels needed to save life and were it to prove impossible to raise these levels through further voluntary donation, then the government would have a responsibility to look at providing some form of inducement. Such, however, is unlikely to be the case and voluntary donation is expected to be sufficient for life-saving intervention. Life prolonging donations such as those used in heart or kidney transplants become life-

saving donations when an individual needing such a transplant comes near the end of life. Of course it is not possible to respond with immediacy to such a situation; there is a need for a steady stream of organs for transplantation and many of these can only be donated after death. What is required is a large bank of organ donors who have registered for donation upon death. It may be argued rightly that, if an individual was aware that, after death, his or her organs would be used to save a life that would otherwise be lost, then there is a moral duty to donate. The difficulty lies in assuring individuals that such would be the case (not all donated organs do, in fact, result in transplantation for a variety of reasons). Most transplants occur while the recipient's death is probably still some months or years away. This represents good medical practice since recipients often have to be in reasonable health in order to benefit from a transplant operation. In these circumstances, donation may be properly seen as life-prolonging rather than life saving and, as such, it is difficult to persuade most people that they have a moral duty to become donors. While it is laudable that many people wish to donate bodily material in order to enhance or to create life or for research purposes it is difficult to see on what basis these actions could be said to be indicative of moral duty rather than an expression of altruism or solidarity. While altruism itself may be seen, by some, as a moral imperative individuals have to make choices between which altruistic actions they will take during their lives. Even if it may be correct to say that everyone has a moral duty to act altruistically it is not correct to prescribe which altruistic choices individuals must make. It is also unreasonable to believe that any human being will act only in an altruistic manner on every occasion and in every context; to attempt to make altruism into a universal moral duty rather than a moral choice would undermine the concept of altruism and would most probably lead, in practice, to fewer altruistic choices being made.

Question 13

A moral duty to participate in first-in-humans trial may reasonably be thought to exist where all the following conditions are met: an individual hopes to benefit directly from the development of a particular drug; he or she is considered to be an acceptable candidate; he or she is able to take part in the trial given family, work and other commitments; there are no unreasonable risks involved in the trial. Apart from the above circumstances, it is difficult to see that a moral duty to participate would exist even though some individuals may feel that to act altruistically is a moral imperative that leads them to volunteer for such trials. As stated in the answer to Question 12, altruism may indeed be properly viewed, by some, as a moral imperative but it is not possible for any given individual to act in every conceivably altruistic way during the course of his or her life. Choices have to be made between which altruistic actions an individual will take. There are no grounds for saying that participating in a first-in-humans trial ought to take precedence over other altruistic actions.

Question 14

In general, it is right to seek to meet demand for life-saving and life-prolonging treatments and, as argued previously, these ought, on balance, to receive priority consideration in most cases. As noted, previously, however, life-creating donation is likely to be viewed by many prospective donors as being different from other types of donation and so it is possible to promote gamete and embryo donation (if viewed as being ethically acceptable) without this having a detrimental effect on other types of donation or treatment. Research that may lead to life saving or life prolonging treatment also deserves priority over other types of research, although here again, research that may lead to better fertility treatment is likely to 'stand alone' and, if deemed ethically acceptable may be promoted as such. With regard to life-enhancing treatment the demand is potentially endless, depending on the levels and types of enhancement considered. Since economic and personnel resources are limited as is the supply of donated material it is both unrealistic and undesirable that every type of life enhancing treatment ought to be afforded equal priority. Treatments dependent upon donation that may, for example, restore sight or result in total facial reconstruction are of such importance that they, rightly, ought to be given priority over other treatments that are likely to have a less significant impact on a recipient's life. Such decisions are, of course, to a degree subjective, but given the limited resources available, such decisions, nonetheless, have to be taken.

Question 15

In order for consent to be truly free it is essential that there is no element of direct or indirect coercion or manipulation involved in the donation process. This is true for information and recruitment campaigns where emotional or 'moral' pressure may be brought to bear on prospective donors. It is also true in the area of incentives. It is right that no one ought to be financially penalised for donating material, hence the payment of reasonable expenses is acceptable. Great care ought to be taken in going beyond offering payment of expenses, however, regardless of the type of donation under review. Incentives such as badges or other ways in which individuals may receive public recognition for donation may have a manipulative effect on some vulnerable people. Any payment that, in effect, offers a financial profit in return for donation not only commodifies human bodies but is also rife for exploitation and manipulation. While it is reasonable that individuals who take part in first-in-human trials ought to be compensated for their time since they are not able to be economically active during the period of the trial, any payment ought to be restricted either to compensation for lost earnings or, if an individual is not employed, compensation set at minimum wage levels. In any event, participation in such trials ought not to be seen as employment. It is true that in many areas of employment, payment reflects both risk and responsibility (airline pilots get paid more than taxi drivers), but it is not acceptable in employment practice for people to be paid in order to take risks that they would not otherwise undertake in the course of their employment. Similarly, it would be wrong to correlate compensation and risk in first-in-human trials. Offering some

form of preferential fertility treatment in exchange for gamete or embryo donation is manipulative and potentially coercive and the practice ought not to be permitted.

Question 16
Incentives that may lead to the 'commodification' of human bodies are unethical in that they risk undermining human dignity as well as compromising personal and social relationships. Any incentives that are likely to compromise free and informed consent are unethical. While it is not possible to safeguard completely against the risks of manipulation or coercion it is reasonable to view the following as unethical: Emotional or psychological incentives or disincentives that may result in individuals donating out of guilt or fear; Social incentives that either reward donors by giving them enhanced social profiles or that socially penalise non-donors (creating 'heroes' and 'villains'); Financial inducements that are likely to bring pressure on some individuals to donate in order to improve their finances. There is no difference between such incentives or disincentives being offered by family or friends or on an 'official' basis since the potential impact on an individual making a free and informed choice is the same.

Question 17
Incentives that risk 'commodifying' the human body; 'Incentives' that promote guilt or fear in order to increase donor levels; Incentives that place emotional or psychological pressure on individuals to donate.

Question 18
No, since the incentive is the same: financial profit.

Question 19
There is a difference in that compensation for lost earnings, travel expenses, etc ensures that individuals are not financially penalised for donating or taking part in a trial. All other forms of compensation result in financial profit and, as such, are open to having manipulative or coercive effects on individuals as well as leading to the commodification of human bodies. Some first-in-humans trials may occupy a significant period of time during which participants are unable to work. Those in employment ought to be compensated for lost earnings. Individuals who are unemployed will be unable to seek employment or to take up a job offer during this time. Consequently, it is reasonable to offer compensation at minimum wage levels to offset potential financial loss. Participation in such trials ought to be time-limited, however, so that, in effect, they do not become an ongoing source of financial gain, potentially compromising valid consent.

Question 20
Xenotransplantation: this has already been proved to be effective in the use of pig heart valves and with ongoing research into human-animal chimeras it is likely that further effective uses of xenotransplantation will be found; organ-cell

encapsulation: there are promising reports that injecting encapsulated liver cells from a donated liver deemed not to be suitable for organ transplantation has enabled recipients to achieve improved liver function, prolonging life and potentially avoiding the need for a transplant. Further progress in this field is likely; Stem cell research is likely to lead to the successful growth of healthy differentiated cells and possible whole organs, making some transplantation unnecessary; Improved surgical techniques such as ventricular remodelling may make some transplantation unnecessary; Split Organ Transplantation: split-liver transplantation has already been successfully achieved; Preventative Measures: Health Promotion initiatives have the potential to reduce the need for some organ transplantation.

Question 21
Please see the answer to Question 16

Question 22
With regard to organ donation, altruism and coercion are the two extremes in the spectrum of human relationships. At either extreme it will be relatively easy to discern the motivation for an individual acting as a donor. Towards the middle of the spectrum, intentions and motivations may only be discernible during a process of effective counselling that ought to precede any recipient-specific donation. Particular attention ought to be given, during pre-donation counselling, to the possibility that an individual's consent is not genuinely free and informed because of familial pressure.

Question 23
Where possible, bodily material ought to be donated with: consent being given for certain purposes only; consent being withheld for certain (additional) purposes; consent being given for general (additional)purposes. Consent forms ought to reflect this. Where material has already been donated for specific purposes but the donor's consent was not sought for other purposes, then every attempt ought to be made to contact the donor prior to making additional use of the donated material or information. Where it is not possible to contact a donor, additional use may be made where: anonymity of the donor is assured; the purposes for which consent was given were not, by their nature, so specific as not to allow for additional purposes; the use to which the donated material is put does not raise new ethical issues.

Question 24
In making a decision on behalf of someone else the determining factor must be that the decision is in the best interests of that person; making a decision for oneself may involve acting against self-interest in favour of another person(s) or in deference to a principle. Particular care ought to be taken not to impose a 'moral duty' on another person or to assume that he or she would wish to act altruistically, if able to give consent. At the same time, altruistic motives ought not

to be automatically denied a person who is unable to give consent. Careful counselling and proper investigation may allow for a decision that results in a person unable to give consent becoming a donor if, given that person's character and relationships, acting altruistically is genuinely seen as being in that person's best interests as well as in the interests of the recipient(s).

Question 25

Where the deceased person's wish to be a donor is known and this has been communicated to the family prior to the deceased person's death the deceased person's wish ought to be respected even if family members disagree. Where the deceased person's wish to be a donor is known but has not been communicated to the family prior to the deceased person's death, the agreement of the first 'qualifying' person ought to be sought. Where agreement is forthcoming then the deceased person's wish ought to be respected even if other family members disagree. Where agreement is not forthcoming the welfare of family members ought to be taken into consideration when making a decision whether or not to act according to the deceased person's wish. Individual decisions will vary according to individual circumstances but, as at present, family members ought not to have an automatic right to veto the deceased person's wishes. This is particularly so where the deceased person had formally (eg. in writing, in an 'advance directive, by carrying a donor card or by registering as a donor)expressed his or her wish to be a donor; an informal wish, expressed verbally to health professionals, for example, may prove more difficult to fulfil. Where the deceased person's wish not to be a donor is known this ought to be respected whether or not family members were aware of this prior to the deceased person's death. Where the deceased person's wishes are unknown the first 'qualifying' person ought to be consulted and he or she ought to be encouraged to discuss the issue of donation with other family members. The decision of the first qualifying person ought to be respected. In all circumstances where a person has indicated a wish to be a donor he or she ought to be encouraged to communicate this to family members.

Question 26

A body or its parts ought not to 'belong' to anyone in the sense of a body or its parts being seen as property. An entitlement to use or dispose of a body or its parts ought to be assumed to belong to the person incorporated in that body while he or she is alive. This ought to include the entitlement to grant others partial entitlement to use that person's body or its parts as well as the entitlement to direct how a body or its parts may be disposed of. Where an individual has not made clear his or her wishes for the use or disposal of his or her body or body parts after death a qualifying person may indicate how that body may be used either by way of utilisation or disposal. In either case it is better to think in terms of entitlement to use by way of utilisation or disposal than to think in terms of ownership.

Question 27
No, since to do so is to risk the commodification of the human body or its parts, to risk undermining human dignity, to risk compromising personal and social relationships and to risk compromising free and informed consent.

Question 28
Any medical or scientific knowledge gained from the donation of bodily material or from first-in-human trials ought to be made available to the medical and scientific communities. Particular ways in which companies have made use of this information in patenting drugs or in devising treatments ought to remain the intellectual property of the individuals or companies concerned unless there is an over-riding public-interest argument to the contrary (a 'cure for cancer', for example ought not to remain exclusively in the hands of a commercial company).

Question 29
A person ought to be entitled to state the purposes for which his or her body or body material may be used either by way of utilisation or disposal. This does not imply that an individual must be accepted as a donor if his or her wishes were to be characterised as being discriminatory on the grounds of religious belief, political opinion, race, age, marital status, sexual orientation, gender, disability or social status.

Question 30
The terms of reference ought explicitly to cover information gained from donation as well covering the purposes for which bodily material may be donated. This has particularly relevance for genomic information.