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.

European Society for Organ Transplantation Council

Question 2

Reproductive tissues as eggs and sperm and embryos require special considerations. Donation of such tissues should be guided by a frame work adapted to the fact that these tissues can be used to give rise to new individuals. Regulation should address the specific problems e.g. the protection of genetic integrity as well as how to balance the wish from children to have information about their genetic parents against the donors wish to remain anonymous. Donations of such tissues thus differ significantly from organ donation.

Question 3

This response is focused on organ donation. Yes. An obvious difference is that the live donation carries a risk for physical, psychological and social complications that does not exist in deceased donation. Major concerns in live donation is how to protect the live donor by relevant preoperative evaluation and information, how to obtain a truly informed consent, how to avoid coercion and how to guarantee a long-term follow-up and access to treatment for complications related to the transplant procedure, also discussed in the Reports from the Amsterdam Forum on live kidney donation (Transplantation 2004;78(4):491-2) and the Vancouver Forum on live donation of non-renal organs (Transplantation 2006;81(10):1386-7. In deceased donation there is no risk to harm an individual but instead there is a need to show respect for the dead individual and the grieving family. Issues that need to be discussed/regulated include the definition of death, the diagnoses of death and (in donation after cardiac death) length of a no-touch period. Issues related to respect for the dead body and the grieving family and to who decides about the body of a dead individual are also important. There are also often major differences in the decision making. In live donation, the donor should make an autonomous decision, though often after discussion with his/her partner or close family. In deceased donation, the will of the potential donor is often unknown. The role of the family then becomes more prominent. Depending on the national regulation, the family may have to try to interpret the will of the potential donor or have to make the decision. In some countries with presumed consent, the family still has a right to put their veto on donation. Both live and deceased donation is dependent on that the public has confidence in the health care system and in the regulatory frame work.

Question 4

This response is focused on organ donation. Live organ donation carries a risk for physical, psychological and social complications that does not exist in deceased donation. The live donor may also be under pressure from family or friends. In countries with poor social welfare, the donation may also put the donor family in a

difficult situation especially if complications occur. The evaluation may reveal so far unknown conditions which can be seen as a positive side-effect for the potential donor, at least if treatment is provided. Still follow-ups of altruistic live donors show that there is also a significant benefit for the live donor in being able to help a family member (or friend or sometimes even an anonymous recipient) to a new and better life. Some donors describe this as one of the major positive experiences in their life. Very few report that they regret the decision to donate. This is in sharp contrast to follow-up of paid donors in Pakistan, Iran and the Philippines where a vast majority report side effects and that they regret the decision to donate. In e.g. Moldavia reports describe a social shame and high number of depressions among paid donors. In deceased donation there is obviously no risk to physically harm the donor. However, the donation request could be seen as a burden for the grieving family. Follow-up with relatives to deceased donors often show that donation can be seen as something positive in that their loved one could help others. Well-trained and secure staff has been shown to be of great importance for the outcome of the donation request and for how the family experienced the procedure.

Question 6
Bodily material can also be provided for educational purposes. One possibility is donation of the whole body to a medical university. Another is donation of smaller parts, e.g. the auditory bones for surgical training.

Question 7
This response focuses on organ donation. It seems reasonable to differentiate between different kinds of tissues and different purposes. It should be possible to donate organs and tissues for transplantation without at the same time having to agree to donate for research and educational purposes. Individuals should also have the possibility to make exceptions for certain organs or tissues. "Yes to donation" should not automatically include reproducible tissues.

Question 9
The list includes the main ethical values relevant for organ donation with one exception, the principle of non-maleficence. This principle is relevant in discussions of live organ donation. Follow-up of paid live donors indicate that this practice violates the principle of is definitely violated in pay. Organ transplantation is life-saving, life-prolonging and improves quality of life. In most cases, organ transplantation is also the most cost-effective treatment. In this context "maximizing health and welfare" could be interpreted to include an economic aspect.

Question 10
This response focuses on organ donation and transplantation. In live organ donation, altruism and autonomy are of high priority to protect the free non-coerced choice of the donor. Still donor autonomy cannot over rule medical

judgment and decision-making. Adequate donor information, evaluation and selection are required to fulfill the basic principle of non- maleficence. A positive out-come for a recipient cannot justify long-lasting harm to a live donor. Solidarity is also of great importance and likely to be the basis for the decision to donate both during and after life. Discussing organ transplantation and the allocation of donated organs, a reasonable balance between justice and maximizing health and welfare should be sought. Thus, there is not a single value that always should take precedence.

Question 12
This response focuses on organ donation. In a country that has decided to establish organ transplantation at least three things are needed, the state has to provide a regulatory frame work, the health care system needs expertise, organization and resources to provide donation and transplantation services and the population needs to be willing to donate. In a democratic country, the decision to have donation/organ transplantation could be seen as a decision made by the citizens and thus it could be argued that there is a moral obligation to contribute by donating your organs. On the individual level, however, the individual should have a choice both regarding donation during life and after death.

Question 14
This response focuses on organ donation. It seems reasonable to try to meet the demand of patients that have been considered suitable for transplantation. However, that does not mean that a demand can justify all kinds of measures. Criteria for accepting patients for the transplant waiting list differ between countries and may well be influenced by the organ shortage. In general, it seems reasonable to give the highest priority to life-saving procedures, followed be life-prolonging and then life-enhancing.

Question 15
This response focuses on organ donation. Financial incentives for providing organs for transplantation can be coercive and should be prohibited. ESOT supports the WHO position that cells, tissues and organs should be donated freely without any monetary payment or other reward for monetary value (Guiding principle 5). It seems reasonable that organ donation is cost-neutral. Donors should not be punished by losing money or having to pay for their donation, neither should donation after death cause expenses for the family. This position is in line with WHO Guiding principle 5 and the proposals in the Istanbul Declaration. Recognition could be an acceptable way to promote organ donation and express a societal gratitude as long as the recognition does not have a monetary value, then it may become coercive. The wish of some donors/donor families to remain anonymous must of course be respected.

Question 16

Incentives that are coercive threat the live organ donors possibility to give a free a informed consent.

Question 17
This response focuses on organ donation. In organ donation, introduction of payment to donors will risk the altruistically based donations. International experiences indicate problems to introduce deceased donation in areas where paid donation of live donors is established. Donation will be limited to the groups in society that are in need of money, the poor and the vulnerable. There is also a risk that the potential donor will conceal parts of his history that would risk disqualifying him as donor.

Question 18
Yes, the risk for influencing the decision making and to attract poor and vulnerable groups seems greater with direct financial compensation. Still, in many societies free treatment or funeral expenses may also be coercive. However, it is important that the live donor not is disadvantaged by the donation. The live donor should be entitled to free treatment of complications to the donation and of diseases risking the function in the remaining kidney. It could be reasonable that the economical situation of the donor/donor family is protected e.g. by a life and health insurance related to the donation. Such protective measures are especially important in societies with poor social welfare.

Question 19
This response focuses on organ donation. Yes, there is a significant difference. Donation should be cost- neutral. Compensating for discomfort and pain is hard to distinguish from paying for the kidney or the act of donation and risk to become coercive.

Question 20
This response focuses on organ donation. The incidence of terminal organ failures varies significantly between countries. One recently published example is the difference in frequency of end-stage renal failure in Norway and USA. Prevention of disease, treatment of diseases that may risk kidney function (e.g. hypertension and type 2 diabetes), and protective measures to preserve kidney function as long as possible should significantly affect the need for transplantation. Education, information, access to health care and medication are factors that differ between countries and influence the frequency of end-stage renal failure. Another way to reduce the lack of organs is to improve long-term function and reduce need for retransplantation. Also here, education, information, access to health care and medication are important.

Question 21
This response focuses on organ donation. Incentives that are coercive make it

impossible to achieve a truly valid informed consent. It can be discussed whether an incentive always is coercive for all individuals. Developing guidelines and regulations it seems reasonable to try to protect also the most vulnerable groups

Question 22
This response focuses on organ donation. This is certainly difficult of live organ donation. The live donor should be informed repeatedly during the evaluation about the nature of the intervention. The donor should be capable of understanding the information and competent to make a decision. The degree of understanding should be evaluated. It should be pointed out repeatedly that the donor has a free choice and a right to withdraw during the whole process. The team evaluating the donor should not be responsible for the care of the recipient, a specific donor advocate could be considered. Trained staff able to communicate and take social and cultural differences into consideration is important.

Question 23
This response focuses on organ donation. It could be if it is acceptable in the eyes of the public. Thus it depends on the national context. Ethics Committee approval should always be required. Clinical use of a donated organ should always have priority. This possibility should be used with great care not to risk the public confidence in the donation process and thereby reducing further the access to organs for transplantation.

Question 24
This response focuses on organ donation. There are studies showing that the willingness to give consent to donation after death is significantly lower when asked to decide for a relative who´s wish is unknown compared to when deciding for yourself. In one study donation rates went down by 30%. During life, the individual can make an informed autonomous decision regarding donation after death. A substitute decision maker either, and preferably, tries to interpret the will of the deceased potential donor or is governed by his/her own attitude to deceased donation. As a rule, minors and individuals who are incapable of making informed decisions should not be considered as potential living donors (World Medical Association Statement on Human Organ Donation and Transplantation and Reports from the Amsterdam forum and Vancouver forum on live donation referred to earlier in this document).

Question 25
This response focuses on organ donation. Basically, the will of a deceased person should be respected. It is as important to respect a Yes to donation as a No. Usually the family wishes to fulfill the last wish of the potential donor. If the patient is known to be positive to donation, an immediate negative reaction from the family is often a part of the chock reaction and requires professional and respectful management from the medical staff. If the will of the deceased person is

unknown, regulations vary in Europe. It is important that a national regulation mirrors the opinion of the informed public. Especially in countries with opt-out systems, the public should be well informed and the procedure to opt out well-known and easily available.

Question 27

This response focuses on organ donation. The revised WHO guiding principles state that cells, tissues and organs should be donated freely, without payment or other reward of monetary value. The Istanbul declaration on Organ Trafficking and Transplant Tourism is strongly against the buying and selling of organs and underlines that all countries have a responsibility to help to avoid organ trafficking and transplant tourism. ESOT supports these stand points and have endorsed the Istanbul Declaration.

Question 29

This response focuses on organ donation. In deceased organ donation, the allocation of donated organs should be based on justice and maximizing health and welfare thus directed or conditional donation of organs should be avoided. This position is in line with WHO guiding principle 9: The allocation of organs, cells and tissues should be guided by clinical criteria and ethical norms, not financial or other considerations.

Question 30

As stated in the Istanbul Declaration, organ trafficking and transplant tourism has grown into a global problem. Patients from rich countries travel to receive organs from poor donors recruited from vulnerable groups. Those donors are exploited and undergo minimal evaluation, receive poor care and have no access to follow-up. All countries have a responsibility to work to achieve self sufficiency regarding organs for transplantation and develop laws and guidelines that counteract organ trafficking and transplant tourism. ESOT would like to underline our shared responsibility for these problems and supports the principles stated in the Istanbul Declaration.