Question 1

We feel most form of human bodily material removed, used for research or donated could potentially raise ethical concerns. We assume the following additional areas are included Thymus transplantation, Tissues include bones, tendons (both referred to as musculoskeletal grafts), cornea, skin, heart valves. For the future more difficult areas are already appearing e.g face transplantation

Question 2

We can only reply for our own specific area e.g vital organs; heart, kidney, liver, lungs etc

Question 3

Our main experience is with Kidney, Kidney pancreas, donation where there are significant differences in the following areas; Ethical, Legal, Protocol/ Procedure, Family, Social and Cultural/ faith perspectives between Live Donation, Brain Stem Death Donation and Non Heart Beating Donation.

Question 4

Living Kidney Donation

All living donors must be fit to comply with donation requirements. To comply with this requirement a complete set of health checks are carried out on the donor. If anything that would put the donor at risk is identified in the health checks the donation will not proceed. In some cases overweight donors may be required to lose weight before the transplant operation can commence.

Whilst everything possible is done to eliminate risk to the donor it is acknowledged that the risk of Donor death is 1:3000. Success rates are high 95% but failure can be tragic for both Donor and recipient.

National Guidance exists covering Renal donor Cost / Expenses. Reasonable out of pocket and loss of income expenses incurred by the donor are provided for by the Trust. Some Trusts do cap the claim at circa £5000 to limit their exposure. Self employed donors do have more difficulties usually in substantiating claims. Local policies are developed by Trusts / Commissioners based on guidance. Some Trusts do not publicise the availability of financial assistance. The scheme has been designed carefully to ensure the reimbursement is not seen as incentivising donation.

There is no doubt that for the right patient at the right time a transplant is the best treatment option with a good transplant giving circa 60% of the function of two

normal kidneys (compared with only 5% from either form of dialysis). Quality of life improves considerably and graft survival with many reaching 10 years plus. A transplant is not however a cure and a stable recipient would still have the kidney function of a patient with Chronic Kidney Disease at stage 3.

Living donors continue to live normal lives with no real restriction many experience significant feel good factor. Evidence shows that there is no affect on life expectancy.

The Cadaveric Donation

This presents the family with difficult emotional decisions. In reality circa 40% of relatives refuse donation even in cases where the patient has registered their desire to donate. In the present system a family or relatives reluctance will tend to override a donors registered request.

The donor must be checked not just for matching but also medically to ensure no disease or risk factors are passed on to the recipient.

The identity of donor and recipient are kept confidential in the majority of cases. There are no financial arrangements involved and the donation is truly altruistic

Those families who accept donation in many cases find comfort in the fact their loved one has helped in some cases to save more than one life. Conversely the recipient can in some cases suffer guilt in that a person (identity unknown) had died to give them life. Patients can in these cases often need support. The donor Family will be offered bereavement counselling if required.

The benefits to the recipient in health gain terms are as previously stated.

The ethics involved in Cadaveric donation are complex and can contribute to problems with potential Donor identification.

A patient only becomes a potential organ donor when death is confirmed following clearly defined tests of the brain stem, in which case donation after brain stem death may be possible, or when a decision has been taken – in the best interests of the patient – that further active treatment is no longer appropriate and should be withdrawn, in which case donation after cardiac death (non-heart beating donation) may be possible. This change of emphasis can only occur when critical care staff have complete confidence in the means by which death is certified, there is a clear framework that ensures that there is – and is seen to be – no conflict of interests, and that steps to facilitate organ donation are clearly lawful.

The legal position with regard to non-heart beating donation has been less clear, in part because it differs across the UK. Particular concerns have been expressed on the extent to which, for example, the timing of withdrawal of active treatment may be influenced by delays resulting from the time necessary to complete the retrieval arrangements. This is now progressing

There are concerns however about organ donation after cardiac death where a conflict of interests may be felt to arise between the duty of care of the doctor to the dying patient who is a potential donor after death and the steps needed to facilitate donation. This is an area that raises many legal and ethical issues and a range of differing opinions. It is essential that these concerns are resolved. The legal issues could be addressed through the Mental Capacity Act and/or the Human Tissue Acts and/or their respective Codes of Practice. Organ donation can present many difficult ethical dilemmas but currently there is no single formal body to which clinical staff may turn for advice and resolution.

Question 5
We have limited experience in this area, although renal drug trials, for research purposes are carried on renal patient volunteers

Question 6
In present Kidney donation it has been possible for a directed donation in live donation to become a non-directed donation, as in a recent case where the donor died before the transplant took place. The donation of the organ continued after death but the organ was placed on the open list as apposed to being given to the original directed /related recipient. Concerns were expressed at the ethics of such a ruling and it has been subject to a reappraisal. We are informed amendments to the ruling are in process.

Question 7
As an organisation we could only support altruistic organ donation that complies with present UK ruling or any future national ruling we believed to be in the interest of our patient members.

Question 8
Our members do take part in trials but as long term condition patients the medicines in the trials would generally be directly associated with their care.

Question 9
Respect ; for the decisions of the individual e.g."the person who may not want to donate for whatever reason".
Confidentiality: the identity of the cadervaric donor/ the family / recipient. For the position of a living donor who for personal reasons wants to drop out of a donation at any stage.

Consent Amongst some clinicians there is a certain amount of concern that carrying a donor card, or even registration with the donor register falls short of what would usually be defined as consent in a medical setting. Validity of consent is also issue

Question 10
Autonomy, Altruism, Consent, Confidentiality, Respect, Dignity, Maximising health and welfare, Justice

Question 11
Where a solid organs such as a kidney is being donated then Altruism should be the prime motivation with "compensation" by way of out of pocket expenses, loss of income as previously described and laid down in guidance. Donation should in no way be incentivised financially. Drug trials less significant material may perhaps be compensated for by virtue of time given, expense incurred. Risk is a more difficult consideration and is generally not generally financially compensated

Question 12
No - it is the right of the individual to make there own choice and have the freedom to do so. Moral duty can easily be interpreted as pressure by society for an individual to make a decision e.g. a family member being made to feel morally bound to donate by his relatives.
Does a family have the moral duty to honour a patient's registered request to donate. As relatives and families regularly say no and the donation system usually acquiesce the system and many families would seem accept there is no moral duty. A culture of normality is needed in donation - in the public acceptance and in the Hospital staff attitudes – donation needs to become normal.

Question 13
No - it is the right of the individual to make there own choice and have the freedom to do so

Question 14
We can once again only comment from our own experience as an organisation. Where people are dying unnecessarily due to the inadequacies of a system, as in organ donation, demand should be met.

Of the 25,000 Kidney Patients on Dialysis in the UK, 3,000 die every year, 400 of whom die whilst waiting on the Kidney Transplant waiting list. The Kidney Transplant List is currently 7,000 strong and yet only 7 transplant operations are carried out each day.

Every day In the UK, it is normal for 1,500 people to die, 400 of those are known to have signed up to the Organ Donor Register. Because each person has two

kidneys, that is 800 potential life saving kidneys available every day, yet only 7 operations are carried out. If the NHS could manage 7 more operations a day then the waiting list could be eliminated within three years, but it does not happen and patients continue to languish on Dialysis, or die. The people who choose in life to sign up to the register want to save lives, they do not expect that their organs will be cremated or buried.

Not everyone makes a suitable donor, and not everyone dies in circumstances where organ donation is possible, but kidney patients only need 7 more operations each day out of the possible 800 a day that become available.

Despite the report published by the Organ Donation Taskforce, and the many improvements to the existing system they propose, the NHS is organised is such a way that people will only be considered as possible donors if they happen to die in Hospital, despite their declared wish during life to be a donor after their death. The majority of deaths do not occur in hospital and that is why there is such an appalling wastage of organs. It is why there is a denial of the deceased's wishes before death, and it is why so many Kidney Patients continue to die whilst on Dialysis.
It is time that the government and the NHS asked where and how people die, and then considered in what circumstances GPs, institutions, and other organisations, were likely to be aware of these impending deaths, and of those person's wishes about organ donation? There is need for a complete re-think and then re-organisation of parts of the NHS transplantation services. The new service must recognise that donors die outside the hospital environment, and then build in the capability to ensure a proactive and fast moving "community aware" service that can efficiently bring to the hospital the donor, or the protected organs in sufficient numbers to put an end to the appalling waste of human life, and the utter disregard of potential donor's wishes.
French researchers recently suggested that, for kidneys, such donors could provide a "significant proportion of the functional organs provided for transplant"

Question 15
The manner in which Kidney Living Donors are "compensated" for out of pocket expenses or loss of income are carefully laid down in Department of Health Guidance. As previously indicated the scheme has been designed carefully to ensure the reimbursement is not seen as incentivising donation.
Individuals vary in their wish for public recognition of what is regarded as a gift of life, and this may also be true as a generalisation of individuals from different cultural backgrounds.
In the case of organ donation, some may want to forget and to put the past behind them. Other families may shun public acknowledgement of donation but welcome recognition in the form of a personal letter from, for example, the Chief Medical Officer. Others may gain comfort and satisfaction from a public memorial to

donation in general, whilst there may also be families of organ donors who would welcome public recognition of the individual donor's action through a "roll of honour" in a public place.

Question 16

Yes it makes a big difference - If the Government were to introduce a national regulated organ donation incentive scheme of a financial nature. It would be accepted as a formal, legal and official system. No doubt, as in living donation reimbursement, it would have its tax position formalised, giving it the stamp of officialdom.

Families or friends offering direct financial "incentives" to potential donors, in comparison appear, suspect, self serving and unethical.

Often the size of a sum being paid can have a negative affect - a donor receiving reasonable out of income and expense reimbursement would be seen as acceptable, anyone demanding large sums in reimbursement would be viewed with some disdain.

Cultural attitude as to what is acceptable needs careful consideration.

Research is needed to establish the means of recognition that most donor families would appreciate. This may also be needed on incentives

In kidney donation most of the above have been introduced or tried with some success

- Improvement in transplant infrastructure to maximise donations after death
- 'Pooled' living organ donation
- Non-financial tokens of gratitude
- 'Non-cash incentives'
- Compensation arrangements for expenses
- Mandated choice systems (considered but still a point of debate)
- Uncontrolled donation after cardiac death outside hospital

Question 18

In the case of free treatment or funeral expenses the compensation is connected directly to an event e.g. a deceased donation being acknowledged by funeral expenses being paid.

Direct financial compensation is not connected to the event in the same way and may be seen as or considered a payment for the organ. Particularly if the sum is high.

Question 19

Yes economic losses are measurable and can be accounted for, time may also be in this category. Discomfort and inconvenience are notional and open to varying interpretation by the individual.

Question 20

The policy of early detection of Chronic Kidney Disease will stop many patients progressing to dialysis and the need for transplantation. In the USA such a policy has shown success with a flat lining of the renal growth model
A personal portable dialysis machine that can be worn by the patient but that is many years away.
The other possible alternative was the use of Pig Organs (Xenotransplantation) but this has been downscaled in recent years and appears to have little UK support.

Question 21
We agree the main areas are significant financial incentive / undue influence' and the potential for pressure or coercion being applied. In Living Kidney donation great care is taken to ensure consent is valid, the donation is altruistic, the donor is informed about the nature and purpose of the procedure and no coercion is being applied in both the case of the Donor and the recipient e.g. it is equally essential that the recipient is not being coerced into accepting a donation from someone they would be unhappy about taking the risk of donating.
Indirect incentives - offering a person who agrees to donate organs after death a privileged place should they require a donation in life would destroy the credibility of the fairness of an allocation system. Unless of course there was a surplus of organs availability!

Question 22
In Living Kidney donation this is part of the assessment in the workup of the Donor and Recipient. In many cases the Donor has a separate Consultant to the Recipient to look after their individual interests and an independent Consultant (non-renal) carries out an independent assessment interview with both parties. Transplant Coordinators also carry out assessment in some cases with home visits. The Donor can at any time withdraw with the help of the transplant team. This seems to work quite well as illustrated by the growth of successful living kidney donation.

Question 23
No comment

Question 24
No comment

Question 25
This is a difficult issue and 40% of potential donor families / relatives believe they have that right and say no regardless of the previously registered wishes of the deceased.

It is also the case that whilst, overall, families of 40% of potential donors refuse consent at the critical time, this figure is 75% when the potential donor comes from a BME background.

The Organ Donation Task Force after examining the area in some detail recommended more work was needed to understand the differing reasons for non-donation and how best to encourage engagement with the option of organ donation after death.

Question 26
No Comment

Question 27
No

Question 28
No Comment

Question 29
In the case of Organ Donation (kidney) a person should have control to ensure the donated organ is used for that purpose. Should the removed organ not be used for that purpose then further proposed use should be agreed with the living donor or in the case of a deceased Donor their immediate Family. Also see comments on directed / indirect donation.

Question 30
One major issue that may be outside the remit of the report is that of Donation in Kidneys' were to increase dramatically Transplant units may not have adequate resources to perform the increased number of transplants that this report expects, either in terms of staffing (consultants, juniors and nursing), infrastructure (beds, operating theatres etc) but also, crucially, in the support services upon which transplantation depends. For kidney transplants (and for an increasing number of heart and lung transplants) the services of histocompatibility and immunogenetics laboratories are essential.

Commissioners of transplant services must ensure that donated organs are not wasted as a consequence of infrastructure constraints. This is an area of concern for all forms of solid organ transplantation but particularly so for renal transplant units, which are currently commissioned on a local basis.