Kidney Research UK

Question 1

Please note that this list is not congruent with the definition of human tissue in the Human Tissue Act 2004. That Act deliberately excludes gametes, because they are regulated by other means, but its definition does include faeces and body fluids, including (notably from our viewpoint as an organisation with an interest in renal medicine) urine.

Question 2

Yes. Indeed, We would argue that any attempt to treat 'human bodily material' as a single ethical issue, or even a small number of issues, is fundamentally flawed. The problems generated by this approach were illustrated by the debates around the Human Tissue Act 2004, which concentrated on the post-mortem organs of deceased babies, but which (largely without MPs considering the matter) produced legislation that covered faeces and urine. Each different type of 'bodily material', however that is defined, deserves different considerations; and the same type of tissue may demand different consideration depending on how it is obtained (e.g. post-mortem sampling, live donation or surgical resection as part of an operation to remove diseased tissue).

Question 3

Yes. In fact we would draw three broad categories (subject to comment (2) above). 1. Tissue (usually but not invariably blood) donated by the living specifically for research. This is unequivocally a gift. Naturally the donor must not be harmed. 2. Tissue that was otherwise to be discarded, whether down the sluice (e.g. urine) or as 'clinical waste'. Many regard using this in research as a gift, but we would argue that if it is otherwise to be destroyed as waste, the assumption ought to be that it should be made available for the good of mankind unless there is reason not to (such as a risk of any harm to the person whose body produced the tissue) 3. Post-mortem tissue. There is an argument that the inevitable destruction of such tissue puts it into category (2), and furthermore the donor cannot be harmed. However, the fact that post-mortem tissue is a focus for grieving and funeral ceremony, with consequent benefit for the bereaved, makes it inappropriate to consider it in the same category as 'clinical waste'.

Question 4

For the living to donate an organ has obvious physical risks. A blood sample is less risky. Urinating into a bottle is arguably not risky at all. For the dead to donate carries no risk to them (unless you believe bodily integrity to be essential to an afterlife or reincarnation). But its use risks adding to the grief of the bereaved.

Other risks depend entirely on the use of the sample; this is too complex to discuss here, however anonymisation should eliminate these risks. Benefits are to society as a whole, thereby individuals explicitly accepting some responsibility for delivering some of the things that they are often keen to demand as rights. In a discussion of ethics, surely this deserves more weight than it often seems to get!

Question 6
If donated by the living specifically for some purpose, then the risk depends on the nature of the material. Donating eggs is inherently more risky than donating sperm. Some uses of tissue would be regarded by most donors as ethically outrageous – for example, developing weapons of biological warfare. But there are areas that may be regarded as unethical by smaller sectors of the population; e.g. research into contraception, research that uses living animals.

Question 7
The Nuffield Council on Bioethics report on human tissue from 1995 set out how to distinguish between ethical and unethical uses of human tissue. If, by those criteria, a use is ethical then it is very difficult to prioritise because the outcome is difficult to predict. It is tempting to say 'saving life', but hard to predict what will do that. A transplant tries to save life, but may fail. To use a specimen for teaching may seem less important, and often will be; but the lesson learned may over years lead to the saving of many lives.

Question 8
Perhaps broad prioritisation is possible based on the level of suffering caused by the condition.

Question 9
Not if the points raised in our other answers are interpreted broadly.

Question 10
All the values listed are important and we do not believe that any one should take precedence over the others

Question 11
Concerning the provision of human bodily material, we believe that where the material would otherwise be incinerated as clinical waste (e.g. surgically rejected material) there should be a presumption that it is available for any ethically legitimate purpose unless the 'donor' takes active steps to object. This is the position advocated by the Nuffield Council init publication from 1998. Where this does not satisfy the need, and living donors / live healthy subjects are needed, there is a need to avoid financial coercion of donors. The line between 'expenses' and 'payment' is often difficult to draw.

Question 12
Yes. Where the human bodily material would otherwise be incinerated or disposed of as clinical waste (without risk to the original 'owner'), but it could be used to help others, there should be a duty to use it to help others rather than to destroy it.

Question 13
This should be down to individual altruism, but individual altruism needs to be better recognised, praised and encouraged.

Question 14
Demand and prioritisation will always be difficult.

Question 15
Recognition and acknowledgements, however financial incentives are complex and open up other factors.

Question 16
Of course some forms are unethical.

Question 17
Inappropriate levels of persuasion or coercion.

Question 18
Most forms of 'indirect compensation' have a measureable financial value, so the difference is at best small.

Question 19
Yes. The former are easy to measure – ask for receipts. The second are not, so the value of the compensation is hard to decide and will inevitably arouse suspicion of 'payment for donation'.

Question 22
This is very difficult to assess and attribute to the route influence.

Question 23
Yes. To demand specific consent is to assume that for all the other myriad purposes to which human tissue may be put, there is refusal. Where there are special circumstances (e.g. research into contraception, research involving vivisection, as noted above) this may be appropriate and specific consent should be sought. But in general, consent to use a sample for a research projects suggests an individual who is favourably disposed towards research. It is best to check, if that is practicable; but if it is not, a presumption As stated before, if a biological sample is otherwise to be destroyed as waste, the assumption ought to be that it should be made available for the good of mankind unless there is reason not to (such as a

risk of any harm to the person whose body produced the tissue). As recommended by the Nuffield Council on Bioethics in 1995.

Question 24

Yes, as considered in law. How do we decide what is 'best interests'?

Question 25
We believe that if a clear wish has been recorded before death, the situation should be entirely in parallel to disposal of the deceased estate. There may be certain circumstances where the will of the deceased may be challenged, but not many. By default, the wishes of the deceased should override those of the family, perhaps unless those wishes are obviously malevolent. If the wishes of the deceased are not known, the role of the family should be to try to indicate what the response of the deceased if asked before death. We should seek as far as possible to avoid asking the recently bereaved to make difficult decisions.

Question 26
Current law is appropriate

Question 27
No, not under any circumstances.

Question 28
Current law is appropriate.

Question 29
They should be allowed to withdraw consent if they choose to take active steps to do so - unless it is impractical, such as an organ that has been transplanted or a research sample that has been irreversibly anonymised. But consent for tissue use should be regarded as 'durable' unless it is specifically revoked.