Question 1

Although the current legislation (in England, Wales and Northern Ireland, the Human Tissue Act 2004) draws a distinction between bodily material that consists of or contain intact cells and subcellular materials, in ethical terms this is a distinction that seems arbitrary, but probably pragmatic in legislative terms. Primary subcellular components or biochemical extracts (such as nuclei, DNA, RNA, proteins, etc) that have not been significantly modified ex vivo remain of the "essence of the individual" and hence retain ethical implications, even if there are no legal implications.

Question 2

Materials that are capable of being used in the generation of a new individual person, such as gametes, have a special set of ethical considerations.

Question 3

There are ethical and moral differences that result from the following: a) ability to exercise an autonomous continuing interest in the use of the material; b) religious beliefs or cultural traditions relating to death; c) risks to donors. There are real practical differences in the methods of handling and retrieving samples from the living or the dead. There is also a "yuk factor" difference in public perception.

Question 4

Deceased donor: Costs – to relatives – a sense that their loved one is not "whole"; deviation from tradition; deviation from religious observance; potentially where the donor's wishes and the relatives preferences are at odds, there is a sense of guilt about of fulfilling the deceased wishes; dealing with the "disgust" at what might be viewed as a horrific act of material retrieval / harvesting. Risks – few, if any, significant risks to relatives and none to the deceased donor. Benefits – sense of "contribution" and "making a difference". Good potentially arising from the tragedy of death. Living donor: Costs – to donor – financial from loss of earnings or other costs practically associated with the act of donation (where they occur); pain and discomfort. Risks - loss of a vital piece of tissue or organ (e.g. a kidney leaving only one to cope); risks associated with the retrieval procedure; risk of loss of autonomy and control over a piece of your body once the material is stored or in use somewhere else. Benefits – those arising from having participated in an act of altruism; potential benefits to other family members in generations to follow (especially, but not exclusively, in the case of inherited disorders); more rarely a direct effect on the donor's health or wellbeing.

Question 6

Additional purposes include personal identification, such as: in the criminal justice system; identification after death; identification after being "lost" in some way and without adequate memory or proof of identity; paternity testing. These all raise additional ethical and societal issues. Other purposes include those most commonly occurring in health care, such as testing of donated samples for diagnostic, prognostic or prediction / monitoring of treatment purposes.

Question 7
This is difficult to answer. In essence, I do not have any exclusions that I think could not be justified by an individual in appropriate circumstances. Priority should perhaps go to those purposes related to direct clinical care and where there is a direct benefit arising for the donor or some other individual, such as diagnosis, prognosis and prediction of treatment, transplantation, transfusion.

Question 9
Additional "values" may include trust, benefit and custodianship (as opposed to ownership once a bodily material has been removed from the donor).

Question 10
Autonomy should perhaps be the value from which all activity flows. However, we need to communicate better about the potential benefits arising from donation and participation in research such that autonomy can be exercised with good knowledge of the potential societal gains from altruism, solidarity, maximising health and welfare and justice. At present, the systems are too strongly in favour of autonomy above all else, without fair consideration to a wider societal context of autonomous decision making.

Question 11
It is perhaps less mercenary to participate for free, however, in the right circumstances and with controls in place we would have no objections in principle to providing some limited form of compensation to donors or participants. However, this should be controlled to the extent that donors are not encouraged to commodify the human body or present undue personal risk in return for financial gain.

Question 12
I do not consider that there is any absolute and overriding moral duty to provide bodily material in any circumstances. Participation should be on a voluntary basis.

Question 14
It is correct, if affordable for our society, to strive to meet demand by improving supply. Indeed, there is always a sense that not only is there an unmet demand, but there is also an unmet population of potential donors for whom there are practical difficulties providing the opportunity to donate. These practical difficulties

could be largely overcome in many cases with alternative systems, attitudes and resources. Demands that are more directly focused on meeting a clinical care need and where there is a direct benefit arising for the donor or some other individual, such as diagnosis, prognosis and prediction of treatment, transplantation, transfusion. However, this priority needs to be given in a way that is not at the exclusion of less directly beneficial demands. For example, discussions and opportunities for transplantation and research can co-exist, but we sense that the transplant community is often worried about the potential for additional uses interfering with a potential donation for transplantation.

Question 15

I think that there is no one size fits all in relation to the answer to this question. Circumstances vary considerably. If anything is to be given, monetary compensation for time, loss of earnings, pain and suffering, and acceptance of risk should be the minimum. Of course, where a tissue donation happens in the course of normal health care (such as surgical pathology waste material) this may not be justifiable. However, for a healthy volunteer to do something significant such as donate bone marrow, this is a considerable and unnecessary act (from the point of view of the donor) deserving of compensation. Incentives could include other forms of useful support such as defraying funeral expenses in the case of deceased donors (such as has been commonly done for anatomy donations for many years). I am not very supportive of providing donors with “trinkets” such as T-shirts and mugs as these trivialise the act and are probably rarely valued as a reward or incentive. Recognition is something that we do poorly in this country in contrast to, for example, the USA where recognition of contributions to civil society is much more normal. We do not celebrate our donors in this country nearly well enough, and this extends to healthcare professionals who go out of their way and beyond their normal job description to facilitate donations. Celebrating both types of contribution would, in my mind, go a long way to helping the flow of donated tissues.

Question 16

Forms of incentives that generate a donor marketplace, with donors shoppingaround for the best incentive would present real ethical issues. Incentives should be “official” and offered by the system rather than by those stakeholders with a personal vested interest, such as family or friends.

Question 17

There must be some that would fall into this category, but none that can be listed off hand at present.

Question 18

In reality there is little, if any, difference. Any perceived differences are purely cosmetic in my opinion.

Question 19
I think that conceptually there is a difference, but not one that should be overestimated. From a practical point of view, offsetting economic losses alone are unlikely to generate a significant change in donation intention in the absence of also recognising the need to compensate for time, inconvenience and discomfort.

Question 20
In reality, no.

Question 21
Yes. It would be a difficult thing to gauge, however, the potential reimbursement or incentive must be reasonable and not, of itself, provide an economic reason to donate that outstrips the other more altruistic reasons to donate. Otherwise you could create a marketplace where donors or trial participants could seek income or benefits from participating simply to gain the economic benefit, not to help others.

Question 22
In practical terms this could be very difficult to distinguish. Perhaps private discussions between potential donor and the medical staff concerned should specifically and routinely offer a "way out" for the prospective donor, where the "official reason" given to other family members would be based on some technical unsuitability to save the embarrassment of the prospective donor and allow them to escape from familial coercion. Those who were still happy to proceed would have been given a fair and private chance to withdraw from donation without loss of face.

Question 23
Yes, and the Human Tissue Act 2004 was correct to offer this option with appropriate protections (anonymity of donors) and oversight (by a REC). Sample sets / cohorts can be unique and the ideal means by which to study something. It may be impossible, unduly difficult, impractical or uneconomic to return to donors to seek additional consent. In addition, it may even be unethical and cause concern or distress to do so. An example that comes to mind is the study of historical sample archives to investigate the emergence and prevalence of some "new disease", such a vCJD. This could not have been done without the ability to do so retrospectively and in the absence of donor consent. Therefore, it is entirely defensible to utilise this facility offered by the Human Tissue Act to overcome these situations for the greater good. However, in the modern context, it would be preferable for all new participants / donors to be offered generic and enduring consent, rather than specific consent, to offset the future need to frequently use this legal facility.

Question 25:

Family members, no matter how much they oppose something, should have no right of veto after the death of a potential donor over a decision made by a competent donor in life. The deceased donor's wishes should have primacy. We have, as a society, to move beyond the state where family members can exercise a right of veto in the face of a well known or documented consent by a deceased relative. Where a deceased potential donor's own wishes are unknown, there is no reasonable alternative to allowing their nominated person, if there is one, or family members in a qualifying relationship to decide in lieu of the individual. Again, however, I do not believe it is useful for anyone to be allowed to veto the decision of a nominated person or the person in the highest qualifying relationship. If there are clear differences in opinion within a family these people should take these into account when reaching their decision. But once they have done so, it should not be challengeable by others who have another opinion.

Question 26

I am convinced that there is no need to change to the current tradition that nobody owns a dead body or its parts. That is not to say that it is not legitimate for people or organisations or the state to exercise control over bodies and body parts.

Question 27

Subject to my views expressed earlier about compensation, incentives and rewards, I do not think that a person should be allowed to sell their bodily material for any purpose. If they provide bodily material the primary reason should be altruism followed then by fair and reasonable incentives and rewards. Selling simply for monetary or material gain should not be allowed.

Question 28

It is a noble idea, on the face of it, to suggest that companies should share profits or benefits with donors or volunteers. However, from a practical standpoint it is a ridiculous suggestion that would be unworkable in practice, could stifle innovation and the benefits of conducting such work in the UK, and attributing rewards related to the contribution of individuals would be very difficult indeed. Any participant or donor on their own could only be regarded as making a tiny individual contribution to a very large body of knowledge and evidence leading to the success of a commercial product. Society benefits 1) from companies being able to produce a successful product, which is only successful because it works and provides benefits to our citizens; 2) the economic and scientific environment brings such companies to the UK, which in turn provides jobs and corporation taxes to the nation. These societal benefits are more important than the donor or participant's own very small claim for a share of the proceeds.

Question 29

My answer is derived from a perspective of research use of donated bodily material. The key methods of control that a donor should have are 1) to consent in

the first place and 2) to withdraw consent. I do not believe that control exercised through conditional consent for research, other than in broad terms, is either desirable or practicable. If a donor for consent wants to attach strings to their donation they are better not to donate at all. Motives for setting constraints may be questionable and be obstructive to the science they seek to support. For example, setting parochial limits presume that the best science can be conducted in the restricted locality and also suggests that scientists in other countries are somehow inferior, not to be trusted, etc. Denying the right to use certain technologies, such as genetics, presumes that the donor actually understands the implications of doing so. Certain widely accepted taboos or religiously derived restrictions could, perhaps, be built in as limitations in broader terms of consent, such as those related to the development of contraceptives or work towards human reproductive cloning. These might be regarded as societal limitations or controls rather than individual's controls. Setting conditions may also result in a considerable burden for biobankers and researchers to ensure that they do not accidentally break a condition set by an individual donor.

Question 30
No.