Give and take?
Human bodies in medicine and research
CONSULTATION PAPER QUESTIONS

April 2010

NB Before answering these questions it is important to read the background notes in the consultation paper.

1. Are there any additional types of human bodily material that could raise ethical concerns?
Faeces and excreted materials such as breath, urine, sweat, tears, hormones; cerebro-spinal fluid, which could be used for testing/research purposes.

2. Should any particular type(s) of human bodily material be singled out as 'special' in some way?
No.

3. Are there significant differences between providing human bodily material during life and after death?
Consent issues.

4. What do you consider the costs, risks or benefits (to the individual concerned, their relatives or others close to them) of providing bodily material? Please distinguish between different kinds of bodily material if appropriate.

Key: **i** = individual concerned **r** = their relatives **o** = others

Providing ↓	**Costs**	**Risks**	**Benefits**
Blood	**i** inconvenience/time off work, travel **r/o** none	**i** infection, resulting in inconvenience, pain, death **r/o** possible care/support burden, loss of relative/friend	**i** satisfaction of contributing to pool **r** possible benefit as recipient, esp in case of rare blood groups **r/o** benefit, perhaps unrecognised, of having role model
Whole organs/Partial organs/Tissues	**i** inconvenience/time off work, travel **r/o** none unless recipient	**i** infection, resulting in inconvenience, pain, death **r/o** possible care/support burden, loss of relative/friend; death if r&o are recipients	**i** satisfaction of contributing to better life for r/o **r/o** chance of regaining/improving health
Sperm	**i** inconvenience/time off work, travel **r/o** none unless recipient	**i** no significant risk **r/o** NA	**i** satisfaction of contributing to pool **r/o** if recipient, fertility improvement
Eggs	**i** inconvenience/time off work, travel **r/o** none unless recipient	**i** infection, resulting in inconvenience, pain, death **r/o** none unless recipient	**i** satisfaction of contributing to pool/individual **r/o** if recipient, fertility improvement
Embryos & conception products	**i** already inconvenienced by pregnancy **r/o** NA	**i** no additional risks associated with donation? **r/o** NA?	**i** satisfaction of contributing to R&D **r/**o not directly applicable
Whole body after death	**i** none **r/o** delay in funeral / grieving	**i/r/o** none	**i** satisfaction in advance of death of contributing to R&D & training **r/o** satisfaction of knowing relative or friend will be contributing as above

Faeces Excreted materials breath, urine, sweat, tears, Hormones Cerebro-spinal fluid	**i** no significant cost **r/o** NA **i** inconvenience/time off work, travel **r/o** none	**i** no significant risk **r/o** NA **i** infection, resulting in inconvenience, pain, death depending on method of procurement **r/o** none unless recipient	**i** satisfaction of contributing to R&D & training **r/o** NA **i** satisfaction of contributing to healthier life for any recipient / contributing to R&D **r/o** if recipient-chance of regaining/improving health

5. What do you consider the costs, risks or benefits (to the individual concerned, their relatives, or others close to them) of participating in a first-in-human clinical trial?

Key: **i** = individual concerned **r** = their relatives **o** = others

Costs	**Risks**	**Benefits**
i inconvenience/time off work, travel **r/o** none unless involved in minimising above inconveniences	**i** possible unknown side-effects, infection, worsening of existing condition, resulting in inconvenience, pain, death **r/o** possible care/support burden, loss of relative/friend	**i** satisfaction of contributing to advances in treatment/knowledge **r/o** benefit, perhaps unrecognised, of having altruistic role model

6. Are there any additional purposes for which human bodily material may be provided that raise ethical concerns for the person providing the material?

Not aware of any, other than I would be against my material being used in a purely commercial environment.

7. Would you be willing to provide bodily material for some purposes but not for others? How would you prioritise purposes?*

I would be willing to provide any materials I do not need, for any purposes (except the commercial example above), providing there is minimal risk attached to the provision process. I intend to donate my body to research purposes after death, and I am on the organ donor register.

8. Would your willingness to participate in a first-in-human trial be affected by the purpose of the medicine being tested? How would you prioritise purposes?*

I am not willing to participate in a first-in-human trial for any purpose. I consider that I am at too high a personal risk because of my existing renal and cardiac conditions, and my medication, in particular my immunosuppression would probably make me ineligible. If I was in excellent health I wouldn't make any distinction between medical treatment and research. Within medical treatment I might prioritise in the following descending order: Life-saving / Life prolonging / Life-enhancing / Life-creating.

* Some respondents (for example organisations) may wish to respond to these questions by commenting on whether they believe any purposes should be singled out for any form of special treatment or priority)

9. Are there any other values you think should be taken into consideration?

Not aware of any other relevant values in addition to the seven listed.

10. How should these values be prioritised, or balanced against each other? Is there one value that should always take precedence over the others?

Altruism, Autonomy, Dignity, Justice, Maximising health and welfare, Reciprocity, Solidarity.

It is difficult and possibly pointless to try to prioritise these seven values/aims, but I would single out "Maximising health and welfare" as the one, if necessary, to always take precedence over the others.

11. Do you think that it is in any way better, morally speaking, to provide human bodily material or volunteer for a first-in-human trial for free, rather than for some form of compensation?

Yes, compensation should not be part of this.

Does the type or purpose of bodily material or medicine being tested make a difference?

No.

12. Can there be a moral duty to provide human bodily material, either during life or after death? If so, could you give examples of when such a duty might arise?

During life: Yes in the case of 'spare' organ or tissue eg kidney in the case of live family/altruistic donation.

After death: Yes in all cases, especially where lives can be saved or quality of life improved and the organ/tissue in question would otherwise be totally wasted.

13. Can there be a moral duty to participate in first-in-human trials? If so, could you give examples of when such a duty might arise?

Difficult to envisage any case where there is an actual moral duty rather than just the potential for an altruistic value.

14. Is it right always to try to meet demand? Are some 'needs' or 'demands' more pressing than others?
Yes in the case of Life-saving / Life prolonging / Life-enhancing needs or demands, **No** in the case of Life-creating. I cannot generate any enthusiasm for the latter, having adapted to the personal experience of infertility. I can empathise with the despair of a couple wanting to maintain a family line, or a woman keen to experience pregnancy, but there are plenty of children awaiting adoptive parents.

15. Should different forms of incentive, compensation or recognition be used to encourage people to provide different forms of bodily material or to participate in a first-in-human trial?
Incentives should focus on education, greater emphasis on raising public awareness and encouraging altruism. The promise of payment of funeral expenses can clearly be viewed as a financial incentive but I see this as an acceptable exception to views expressed elsewhere because it is tied to a specific expenditure, provided it is an institutional payment and does not involve family or friends.

Compensation should be restricted to reimbursement of travel costs and lost earnings and not include separate financial incentives.

Recognition in the form of certificates and badges of the type awarded to blood donors might encourage altruism, as might greater use of letters of thanks and inclusion in memorial services. Anonymous inclusion of case studies /photographs in media campaigns and promotional/educational materials could be helpful. Participants seeing their inclusion could find it encouraging, even if anonymous. Participants whose photos/cases were not included could be encouraged by seeing the acknowledgement of their peers who had performed the same service.
If your answers to any of Questions 16-19 below would depend on the nature or purpose of the bodily material or the medicine being tested in the trial, please say so and explain why.

16. Are there forms of incentive that are unethical in themselves, even if they are effective?
Yes, money, except in the case of the reimbursement described above.

Does it make any difference if the incentive is offered by family or friends, rather than on an 'official' basis?
No. Any reimbursement should be offered by the NHS or relevant research body, and not family or friends.

17. Is there any kind of incentive that would make you less likely to agree to provide material or participate in a trial? Why?*
The offer of a purely financial incentive/honorarium would slightly discourage but not necessarily deter me from agreeing to provide material or participate in a trial? All other considerations being acceptable, I would agree but decline remuneration.

18. Is there a difference between indirect compensation (such as free treatment or funeral expenses) and direct financial compensation?
Probably not, but I am inclined towards being accepting of funeral expenses being offered institutionally. However, in the case of older folk of limited means this might present the disadvantage of encouraging relatives to apply untimely pressure in order to deflect costs which might fall to them.

19. Is there a difference between compensation for economic losses (such as travelling expenses and actual lost earnings) and compensation/payment for other factors such as time, discomfort or inconvenience?
Yes, because the former compensates for actual costs incurred, bringing the participant back to financial balance point, the latter results in a financial gain.
* Some respondents (for example organisations) may wish to respond to this question by commenting on whether they believe any forms of incentives can be counter-productive.

20. Are you aware of any developments (scientific or policy) which may replace or significantly reduce the current demand for any particular form of bodily material or for first-in-human volunteers? How effective do you think they will be?

Few in addition to the examples suggested; all have the potential to increase the number of patients/conditions treated and/or the effectiveness of treatments, thereby reducing demand. Technical advances, particularly in the fields of early identification and prevention will increasingly contribute to reduction of demand.

If your answers to Questions 21 or 22 below would depend on the nature or purpose of the bodily material or of the drug being tested in the trial, please say so and explain why.

21. In your opinion are there any forms of encouragement or incentive to provide bodily material or participate in first-in-human research that could invalidate a person's consent?

No.

22. How can coercion within the family be distinguished from the voluntary acceptance of some form of duty to help another family member?

It can't in all cases. A family member being coerced might well feel a measure of conscience alongside their reluctance, and then hide the coercion from a medical professional.

23. Are there circumstances in which it is ethically acceptable to use human bodily material for additional purposes for which explicit consent was not given?

The Human Tissues Act exception quoted in the notes where specific consent was given, but not generic consent, sounds reasonable. Is there not a case for a 'hybrid consent' category, where the donor gives specific consent and also signs up to generic consent too, allowing for additional unpredictable uses to be catered for too?

24. Is there a difference between making a decision on behalf of yourself and making a decision on behalf of somebody else: for example for your child, or for an adult who lacks the capacity to make the decision for themselves?

I believe that there a significant difference between making a decision on behalf of yourself and making a decision on behalf of somebody else. The latter should be allowed where it is seen by both carer and medical personnel to be in the best medical interests of the subject, and where there is negligible risk to the subject.

25. What part should family members play in deciding whether bodily material may be used after death (a) where the deceased person's wishes are known and (b) where they are unknown? Should family members have any right of veto?

(a) Where the deceased's wishes are known and were arrived at when the deceased was in full command of their faculties, there should be no family right of veto.

(b) Where the deceased's wishes are not known, the family should have right of veto based on their knowledge of the deceased.

If your answers to Questions 27 or 28 below would depend on the nature or purpose of the bodily material or medicine being tested, please say so and explain why.

26. To whom, if anyone, should a dead body or its parts belong?

The living individual should have the right to bequeath their own their body after death whether their relatives or the state should. Reasonable attempts should be made during this register process to ensure that the possible uses to which the body might be put are made known to the subject. In the event of registration of interests not taking place, the State should by default own the body. If this were ever established in law, a new organisation should be set up to separate the process away from the NHS, so that no perceived vested interest should be evident or claimed to be.

27. Should the laws in the UK permit a person to sell their bodily material for all or any purposes?

Emphatically NO.

28. Should companies who benefit commercially from others' willingness to donate human bodily material or volunteer in a trial share the proceeds of those gains in any way? If so, how?

No, but it might be reasonable to require that their related accounts should be fully transparent to the public, and maybe that the likely allocation of any financial gains for the company should be made known to the prospective donor/trial participant.

29. What degree of control should a person providing bodily material (either during life or after death) have over its future use? If your answer would depend on the nature or purpose of the bodily material, please say so and explain why.

The degree of control both during life and after death should be determined by the terms of formal consent granted during the donor's lifetime. See 'hybrid consent' suggestion in Q23.

30. Are there any other issues, connected with our Terms of Reference that you would like to draw to our attention?

No.