

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.

Royal College of Physicians of Edinburgh

Dear Ms Harvey

Re: Nuffield consultation on ethics of human bodies in medicine and research

The Royal College of Physicians (RCP) is grateful for the opportunity to respond to the above consultation. In so doing, we have consulted the RCP's Committee on Ethical Issues in Medicine (CEIM) and would like to make the following comments.

General comments

- We commend the consultation as interesting, sensible and methodical. Our initial response was to query the proposal to associate first in man (FIM) studies with organ and tissue donation. The idea of loaning a body in this way appeared unusual. However, following debate on the issue there emerged an opinion that this was a constructive approach enabling a new view on these issues. Nonetheless, there does not seem to be anything unique about FIM as opposed to other research. It is further noted that not all FIM studies take place in healthy volunteers and some take place on patients, especially with cytotoxic agents.
- Dignity and putting a price on human bodies may be incompatible in the view of some.
- We understand this report to be more discursive than the usual Nuffield reports - which offer clear policy guidance. We believe this is valuable approach and would like to support the work of the group. However, the report does include some apparent inconsistencies and these require addressing eg potentially constructive comparisons where we note that it seems illogical to be prepared to pay someone to take a risk in a trial, but not to pay for the removal of a kidney.

Consultation questions

1. Are there any additional types of human bodily material that could raise ethical concerns?

Material that gives rise to stem cells should be considered separately and be singled out.

2. Should any particular type(s) of human bodily material be singled out as ‘special’ in some way?

Various cultural groups would attach differing importance to parts of the body. This should be explored.

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

The obvious difference is that consent can be rescinded if the donor is still living and the tissue is being used for research (equally obviously, organs can't be removed once donated by a living donor).

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.

This depends on specifics eg the material, the person. We believe that conflation here is unhelpful and makes the question more difficult to answer.

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?

Overall, we note that FIH trials have a good track record. The benefits are mainly financial for the drug company, particularly when healthy volunteers are used. However, we are concerned about the terminology used (the ‘loan’ of a body). We note that in some trials it was only possible to use unhealthy volunteers - sometimes children who would not understand the potential risks involved - as the treatment would be harmful to the healthy. There were no benefits. Payment could interfere with the capacity to give consent but challenges could be other than financial and should be explored.

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

Stem cell research: consent to use must be unconditional and if it were possible to derive eggs and sperm and so produce a baby, ethical concerns would be raised. Personal views and cultural differences would be important.

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

We note that bodily material is used for purposes other than medical (eg cosmetics), which might affect a willingness to donate. We agree that there are priorities - structured research with an aim of identifying a diversity of perspectives might help in establishing this.

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? * * *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*

Willingness to participate might be stronger if the genuinely needy could be helped (eg those with malaria). There may be less willingness if the aim was to produce a drug similar to others that already existed (eg a beta-blocker). Priorities might be based on a balance of good for others vs. harm to oneself.

We note that most donors operate on an all-in basis.

Under section 2, we would suggest ‘life-restoring’ would be more appropriate than ‘life-enhancing’.

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

We believe that consideration of the inclusion of ‘responsibility’ is necessary. Under section 3, we question what is meant by ‘solidarity’ and suggest separating ‘maximising health and welfare’ into two separate principles - one on maximum welfare and the other on appropriate levels of risk.

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

We believe this to be an insoluble dilemma and operationally impossible.

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

Some believe that there is no such thing as altruism; others have suggested that it is often only possible for the better off who were fortunate enough to have the time and resources to spare, a minority view. Those that were paid are not necessarily less moral, although volunteers do offer something special and we note a respect for those that gave up their time in particular. There is a need to articulate virtue within the document and how it is valued.

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?

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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?

The way duty is understood is crucial to understanding these two questions. The Kantian perspective held that all was a duty, but if duty was considered an obligation or imposition, debate was legitimate. There was always a range of what one could or should do, but this was all in the context of other things. The suggestion in the RCP research ethics guidelines - to the effect that research was for the moral good and had its obligations; all other things being equal one should participate if it were possible to do so – holds good. Participation should be part of the social contract and being part of society is more than obeying the law.

14. Is it right always to try to meet demand? Are some ‘needs’ or ‘demands’ more pressing than others?

No, to the first part as ‘demand’ is dependent on context. Yes, to the second part.

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?

Yes, we see no reason why this should not occur. However, distinctions may not always be good. We note that the laws relating to egg-sharing are incoherent: not part of the NHS and reciprocity is different in the NHS and the private sector.

16. Are there forms of incentive that are unethical in themselves, even if they are effective? Does it make any difference if the incentive is offered by family or friends, rather than on an 'official' basis?

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17. Is there any kind of incentive that would make you *less* likely to agree to provide material or participate in a trial? Why?*

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18. Is there a difference between indirect compensation (such as free treatment or funeral expenses) and direct financial compensation?

The basis for payment in FIH trials appears vague and should perhaps be revisited eg a) should a market rate be paid; b) should the lowest rate be paid; c) should they pay well to ensure the burden of participation does not rest with the less well-off? In the UK, no large incentives were offered, but this is not true elsewhere. The RCP research ethics guidelines note too free a use of the words coercion and coercive. Payment is never coercive and participants can say no, or walk out.

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?

We would query how comfort or inconvenience can be valued. There should be a ceiling for actual expenses and we believe that all trial phases should be included.

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?

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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 comment.

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

The existence of a medical 'duty' and a parallel duty to care for a family member, for example, is noted. There may be a need to distinguish between the two. We believe that more subtlety of language is required as 'pressure' was more likely than actual 'coercion'.

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?

We strongly believe this to be the case eg for a new disease (CJD, HIV are now historic examples). The proviso being, that research is subject to appropriate government or research ethics approval.

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?

We believe so. The recent MMR case demonstrates how consent to research in others may be given by family members desperate for help. However, it is difficult to believe that the actual participants would have viewed matters similarly.

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?

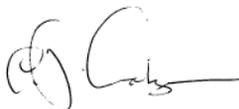
a) We do not believe that families should have a right of veto over previously expressed wishes by the decedent, although it is likely to happen de-facto.

b) We believe family members should have the right of veto, if the deceased wishes are unknown.

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

Control is lost after death. We believe that any research data derived from a participant should be available for use and that it should not be possible for it to be withdrawn once entered in to a database. Indeed, even for the living, withdrawal from a trial should usually mean that no further data can be collected, not that data can be withdrawn. This would be best routinely addressed in consent documents.

Yours sincerely



Dr Patrick Cadigan
Registrar