

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 Pathologists

This is the official response to the consultation from the Royal College of Pathologists. It was formulated by the ethics committee approved by the Research committee and ratified by Council and the President

We elected to respond to only some of the 30 questions

Please acknowledge receipt of this response

Professor David Marks
Chair RCPATH Ethics Committee

Consultation Questions (responses in bold):

We elected to only respond to some consultation questions (numbered)

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

There needs to be a precise consent procedure for after death donation and the rights of the relatives will need to be considered. We did not debate this issue further with regard to specifics

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?

Proper research pathways should be followed. The plain language statement is scrutinised by RECs, volunteers are aware of the potential risks. These trials have more uncertainties about potential adverse effects but provided these are made clear we don't feel there are any special issues here

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?

The donation of material should be voluntary and altruistic. Payment of money (other than incurred expenses) means that the volunteers may only be doing it for financial gain and they can be manipulated. Incentives are problematic in that they turn the donation into a business transaction. The consent process should be clear, transparent and straightforward.

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?

This is a difficult philosophical issue. The beneficiaries of developments that result from research (society as a whole) should also be willing to participate in research studies; society has a collective responsibility. It could also be argued that the individual has a responsibility or duty to participate but that would depend on what was being asked. In living patients the right to not participate is foremost but the issues for stored samples from deceased patients require further deliberation. We did not make a recommendation about the latter issue

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?

Participants in *first-in-human trials*: payments are permitted, with the level of payment to be offered set by those running the trial, subject to the approval of the relevant ethics committee. Industry guidance recommends a payment model based on the minimum wage and emphasises that payment must never be related to risk.

Recognition: we have no issues with this

Compensation: should be related to earnings lost

The committee is firmly against any other incentives: otherwise people will be exploited

Introduction of financial incentives for donation after death, such as meeting funeral expenses

We don't agree with this, this is exploitative

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

Treatment should be free anyway and indeed it is in the UK. Giving some patients better treatment because they participated in a trial is unethical

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

No

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.

There should be one consent procedure which is explicit and comprehensive and after that consent should be assumed. We also suggest that donors of human material be given the ability to opt out of certain potential uses of their bodily material