

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.

British Fertility Society

Responses to the Questions raised in the Consultation Document

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

No comment

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

The BFS believes that reproductive cells which have the potential to produce a new life are different than any other type of bodily material.

Sperm donation, at present, can be used to produce up to ten families, whereas organ donation may only affect one or two people. The onward potential of gamete and embryo donation will have a significant impact on several families. Furthermore, there is the potential for stem cell research to result in several stem cell lines developed from donated gametes or embryos that could help many more people in the future.

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

The BFS believes there is a difference as donations made whilst alive must take into account the risks to the donor and consideration around information, consent and the impact on the family. Gametes cannot be removed without explicit and comprehensive consent for specific use whilst the donor is alive or dead.

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.

The BFS believes that the costs, risks and benefits depend on the nature of the provision. We promote high quality scientific research, and gamete and embryo donation have played a major role in advancing our understanding of fertility and early embryogenesis.

Gamete donation for males is low cost, low risk and has the potential to provide huge benefits to childless individuals. It could also contribute to significant advances in stem cell technology. The main inconvenience is the frequent visits required for screening, and donating samples. In contrast, egg

donation has risks attached, as donors need to undergo superovulation and an egg collection, which is an invasive procedure usually performed with a conscious sedation anaesthetic. During this process complications may occur such as ovarian hyper-stimulation syndrome (OHSS), and at time of the egg collection there is a risk of haemorrhage and infection, which may have an impact on the future fertility of the donor. Again there is a need for regular visits during the course of a donor cycle and the need to take parenteral medication. The benefits are the same as those for semen donation, although usually only one of two childless individuals are helped per donation.

Fresh embryo donation is low risk as spare embryos surplus to requirements may be created during a couple's infertility treatment, in those individuals who not wish to cryopreserve embryos for their own future use. No additional costs would be incurred, but the benefits of donating these embryos for treatment or for research purposes could be very beneficial.

Frozen embryo donation would also pose no risk to the couples as they can chose to donate embryos surplus to requirements to research or to help other couples rather than dispose of them. This is often the preferred option for couples. Indeed, couples are often disappointed on the occasion that there is no research being undertaken to which they could contribute.

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?

The BFS feels that participation in research projects involving egg or embryo manipulation or novel methods of embryo culture could be considered to be examples of first-in-human clinical trials.

However the level of risk and cost will vary with the nature of the trial. For example trials which compromise the chances of a live birth following Assisted Reproductive Technology or result in an abnormal offspring, may have significant costs both for the individuals concerned and in the longer-term society.

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

Gametes / embryos may be used to explore and help to identify whether a specific treatment is feasible for an individual, or an embryo may be used with the purpose to create a child with a particular genetic match to an existing child with a known established disease for the benefit of the existing child, the so called "saviour sibling".

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

The BFS believe that donors should be allowed to prioritise what they wish to have their donation used for in research. For example some couples may be happy to use embryos in research designed to improve the culture environment, which in turn may improve IVF success, but may not be happy to donate to stem cell research. They ought to have this option. It is essential that donors should be given appropriate information and counselling by trained staff not associated with the research project.

The BFS believes that those wishing to donate their gametes or embryos for others to use in treatment should not specify which groups of patients should receive them.

Some members responded indicating they personally would not provide material for developments which are primarily commercial however they would prioritise donation for maximum and immediate clinical benefit i.e. in treatment followed by treatment development.

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?*

The possible risks must be balanced against potential benefits

** 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?

No

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

The BFS believes that autonomy should take priority in the sense that donation must be the choice of the donor. The prioritisation of other values will depend on the individual and the circumstances.

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 issue is whether the donation is fully informed and voluntary and whether incentives prevent a donation from being considered voluntary. If a donor put's themselves at risk for an incentive the voluntary status of the donation may be called into question. Volunteering for trials is very different from donation and there are some materials that can be easily given, with implications restricted to an individual and not to anyone else. There are also

issues regarding what makes people join clinical trials whether it is to help themselves and also what the implications are in the short and long term.

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?

Donation ceases to be voluntary if it is a moral duty. An individual should not be compelled to put themselves at risk on 'moral' grounds.

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?

See above

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

Attempting to meet demand is reasonable but not outside of the normal framework of voluntary donation.

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?

The BFS believes that compensation should be commensurate to the loss / inconvenience to the donor, but uniform to the donation, i.e. egg donation is invasive but short lived, sperm donation is easy but several samples are required over a longer time, embryo donation could be regarded as relatively easy. Therefore, compensation could be varied.

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? Does it make any difference if the incentive is offered by family or friends, rather than on an 'official' basis?

Valid consent means donors must have understood the process, the need and gains to the recipient, the programme or trial, including the personal pitfalls, and the complications. Financial gain or feelings of *good will* can influence consent but if properly discussed can be taken into consideration. It could be argued that direct financial benefits make human tissue/cells/organs commodities.

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

No Comment

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

No moral difference in the type of material benefit

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?

No difference in the sense they simply restore the donor to pre-donor status. It is not unreasonable to ensure a donor is not put of pocket as a result of their donation. See answer to Q15

** 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?

There may be the potential to replace direct donation with tissue/cells developed from stem cells. The BFS supports the continued research in this field.

The developments in egg freezing, and the possible expansion of social egg freezing in younger women potentially could have a small impact on the need for some women to have egg donation. However, this is unlikely to reduce the demand significantly, as egg freezing has a significant cost implication, and as more and more women delay child bearing, the demand for egg donation may indeed expand in time.

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. Please feel free to respond with your own personal opinions, with comment on a range of possible positions, or with your organisation's policy, as appropriate.

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?

The offer of a benefit of high value to the donor, that cannot be obtained through any other route, impacts on the concept of freely given, voluntary consent. Depending on the complexity of donation any compensation should not be enough to be the overriding factor that makes a donor choose to do donate.

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

An assumption of duty on the part of other family members can present as a form of emotional coercion. In addition where a family member is dependent in any economic way their capacity to volunteer is thrown into doubt. Counselling, information giving and time to reflect following this could ultimately distinguish whether the donation is voluntary and should be undertaken by trained staff not associated with the research or treatment.

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 need to consent is not based on the impact of the donation on the donor, but on the use of something that is produced of their body the fate of which, they should be able to influence, with the caveat given in answer 7.

Ultimately the terms of donation should be clear at the time of donation and donors are free to withdraw their consent at any time until they have been used, especially those that donate gametes and embryos.

A more generic consent could be used to allow the use of *residual material* obtained at no risk or inconvenience to the donor, e.g. cord blood and pathology samples, which are routinely discarded.

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?

There is a difference between exercising one's own autonomy and making choices on behalf of others. Application of the *best interest* argument is not straightforward in relation to donation and making such a decision where the donor has no direct benefit could only be done on the basis of guesswork in relation to the donor's wishes.

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?

Family members should not be able to over-ride an individual's wishes as stated during their lifetime.

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?

Control over dead bodies should be permissive rather than proprietorial.

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

Bodily material should not be treated as a commodity and control should be permissive rather than proprietary.

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?

Companies should not share gains in any direct material way.

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 no use of or benefit from a person's bodily material without the donors consent.

The principle of relinquishing control or choice over usage should be the same for gametes and embryos as it is for organs with the caveat in answer 7.

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

None

Comments made by members in relation to other issues:

- (a) What degree of encouragement to provide human bodily material or volunteer in a first-in-human trial is ethically acceptable?

The majority view is:

The word encouragement should not be used in the context of medical research as it suggests inducement, which would not meet criteria for ethical acceptance.

None, beyond a full explanation of the potential benefits of the new therapy being investigated. It must be entirely the couples/individual choice.

Alternative view - This depends on the nature of the material required and how accessible it is. Is an operation required or can the material be obtained without causing any risk to the 'donor' e.g. a pathology specimen which would be discarded. Is the individual going to gain from participation or removal of an organ for toxicity testing.

- (b) Is there a point at which it must be accepted that supply cannot meet demand?

Absolutely - no urging or inducement whatsoever can be allowed.

Yes – where supply has diminished through lack of volunteers who have been subjected to information and counselling.

- (c) What is required for a valid consent to provide bodily material or to volunteer?

Valid consent means that donors have understood the process, the needs, the gains to recipient or research project as well as the pitfalls, complications and issues for themselves allowing a period of time for reflection.

Consideration of any personal gain e.g. financial through to feelings of *good will* will influence consent but if properly discussed this influence can be recognised by them and taken into account.

Consent must be obtained after discussion with a trained member of staff not directly involved in the research project or in providing treatment using the donated cells/tissues/organs. The consent should be witnessed and should clearly state that they have no ownership once the material has been used in the treatment/research.

The person taking the consent should have an understanding of the requirements of the Mental Capacity Act 2005 to be sure that the consent is truly capacious.

Donors giving sperm, eggs or embryos must be aware of the implications of children born and their rights to search for their donor in the future. They should have access to staff trained to help them discuss the issues and be allowed time to reflect before committing. They also need to consider the

implications of the recipient of their donation, perhaps wishing to donate embryos created from their gametes to research in the future.

- (d) What might undermine a person's consent?

Where the donor does not appear to understand the implications of their actions e.g. not Gillick competent or those in an emotional state e.g. undergoing pregnancy loss or those cognitively impaired.

Encouragement, inducement, lacking capacity, too close a therapeutic relationship with the person seeking consent.

Pressure from family member or friend or feelings of having to donate for a child.

- (e) What future control can the 'donor' or 'volunteer' reasonably exert, for example over later uses of donated material?

Once a donor has given the gift they relinquish all ownership or control over future use.

Once donors have given their gametes and embryos for donation and they have been used they have no rights whatsoever over the material.

- (f) What policy implications are there for government, and for intermediaries such as the NHS, pharmaceutical companies, biobanks and private fertility clinics, in a global context where activities that are banned or tightly regulated in one country are permitted in another?

There should be international consensus to ensure biomedical research makes best use of material donated. It would be hugely helpful if the EU and USA Directive could be amalgamated into a worldwide accepted policy perhaps by the World Health Organisation or other appropriate body.

- (g) What consistency of approach should there be, both across the different forms of donation/volunteering and across the different purposes for which people donate/volunteer?

There are big differences between kidney or liver donation which will go to one person with no potential for onward passage compared with the use of eggs, sperm or embryos which have got onward potential.

The principle of relinquishing control or choice over usage should be the same for gametes as it is for organs.

