NUFFIELD COUNCIL ON BIOETHICS

Give and take?
Human bodies in medicine and research

CONSULTATION PAPER

April 2010

How to respond

It would be most helpful if you could send your response to us electronically. Responses can be submitted online via our dedicated consultation website: https://consultation.nuffieldbioethics.org.

Alternatively, you can email your response together with the respondent's form below (electronic document available at www.nuffieldbioethics.org) to: consultation@nuffieldbioethics.org.

If we receive your response electronically, there is no need for you also to send a paper copy. You will receive an acknowledgment of your response. If you would prefer to respond by post or by fax, you may send your completed response and respondent's form to:

Kate Harvey
Nuffield Council on Bioethics
28 Bedford Square
London WC1B 3JS UK

Fax: +44 (0)20 7323 6203
Telephone: +44 (0)20 7681 9619
Email: consultation@nuffieldbioethics.org

For information about obtaining a large print version of the consultation paper, please contact the Council using the above details.

Thank you.

Closing date for responses: 13 July 2010

Web references throughout the consultation were accessed April 2010.

Respondent's form

Please complete and return with your response by **13 July 2010**.

Your details

Name:

_____

Organisation (if applicable):

_____

Address:

_____

Email:

_____

About your response

Are you responding personally (on your own behalf) or on behalf of your organisation?

□ Personal □ Organisation

May we include your name/your organisation's name in the list of respondents that will be published in the final report?

□ Yes □ No, I/we would prefer to be anonymous

If you have answered 'yes', please give your name or your organisation's name as it should appear in print (this is the name that we will use for your response):

_____

May we quote your response in the report and make it available on the Council's website when the report is published?

□ Yes, attributed to myself or my organisation □ No
□ Yes, anonymously*

*If you select this option, please note that your response will be published in full (but excluding this form), and if you wish to be anonymous you should ensure that your name does not appear in the main text of your response. The Nuffield Council on Bioethics cannot take responsibility for anonymising responses in which the individual or organisation is identifiable from the content of their response.

Why are you interested in this consultation? (tick as many as apply)

- ☐ Work in healthcare or clinical research
- ☐ Work in first-in-human research
- ☐ Work directly with donated bodily materials
- ☐ Work in a professional healthcare organisation or research organisation
- ☐ Work in a voluntary organisation such as patient support group
- ☐ Work in commercial organisation
- ☐ Personal or family experience of donating bodily material or participation in first-in-human trial
- ☐ Personal or family experience of benefiting from donated bodily material
- ☐ Academic or non-clinical research interest
- ☐ General interest in the issues
- ☐ Other (please state):

Please let us know where you heard about the consultation:

- ☐ Received notification by email
- ☐ Newspaper, radio or television
- ☐ Nuffield Council on Bioethics website
- ☐ Twitter
- ☐ Other website (please state):

- ☐ Other (please state):

Using your information

We ask for your postal and email address in order that we can send you a copy of the report when it is published and notify you about activities related to this project. (Please note that we do not make your postal and email addresses available to anyone else and we do not include them with the list of respondents in the report.)

May we keep your postal and email addresses for these purposes?

- ☐ Yes
- ☐ No

Would you like to receive our newsletter by e-mail which provides you with information about all of the Council's activities?

- ☐ Yes
- ☐ No

Closing date for responses: 13 July 2010

Nuffield Council on Bioethics

Professor Albert Weale FBA (Chair)
Professor Hugh Perry FMedSci (Deputy Chair)
Professor Steve Brown FMedSci
Professor Roger Brownsword
Dr Amanda Burls
Professor Robin Gill
Professor Sian Harding FAHA FESC
Professor Peter Harper
Professor Ray Hill FMedSci
Professor Søren Holm
Professor Christopher Hood FBA*
Dr Rhona Knight FRCGP
Professor Graeme Laurie FRSE
Dr Tim Lewens
Professor Ottoline Leyser CBE FRS
Professor Anneke Lucassen
Professor Alison Murdoch FRCOG
Dr Bronwyn Parry
Professor Nikolas Rose
Professor Dame Marilyn Strathern FBA**
Professor Joyce Tait CBE FRSE FSRA***
Dr Geoff Watts FMedSci
Professor Jonathan Wolff

*Co-opted member of the Council while chairing the Working Party on medical profiling and online medicine
**Co-opted member of the Council while chairing the Working Party on human bodies in medicine and research
***Co-opted member of the Council while chairing the Working Party on new approaches to biofuels

Secretariat

Hugh Whittall
Katharine Wright
Dr Alena Buyx
Harald Schmidt
Caroline Rogers
Carol Perkins
Audrey Kelly-Gardner
Catherine Joynson
Kate Harvey
Tom Finnegan
Varsha Jagadesham
Sarah Bougourd

The Terms of Reference of the Council

1 to identify and define ethical questions raised by recent advances in biological and medical research in order to respond to, and to anticipate, public concern;

2 to make arrangements for examining and reporting on such questions with a view to promoting public understanding and discussion; this may lead, where needed, to the formulation of new guidelines by the appropriate regulatory or other body;

3 in the light of the outcome of its work, to publish reports; and to make representations, as the Council may judge appropriate.

Working Party members

Professor Dame Marilyn Strathern, former Mistress of Girton College Cambridge and William Wyse Professor of Social Anthropology, Cambridge University

Professor Janet Darbyshire, Joint Director of the NIHR Clinical Research Network

Professor Bobbie Farsides, Professor of Clinical and Biomedical Ethics, Brighton and Sussex Medical School

Professor Sian Harding, Professor of Cardiac Pharmacology at the NHLI, Faculty of Medicine, Imperial College London

Dr Tim Lewens, Lecturer in the Department of History and Philosophy of Science at the University of Cambridge

Dr Gillian Lockwood, Medical Director, Midland Fertility Services, West Midlands

Professor Theresa Marteau, Professor of Health Psychology, King's College, London

Professor Naomi Pfeffer, Honorary Fellow, University College London

Professor David Price, Professor of Medical Law, De Montfort University

Mr Keith Rigg, Consultant Transplant Surgeon, Nottingham University Hospitals NHS Trust

Professor Bob Simpson, Professor of Anthropology, Durham University

Professor Chris Womack, Principal Clinical Histopathologist, AstraZeneca and Professor of Histopathology, University of Manchester

Working Party terms of reference

1. To identify and consider the ethical, legal and social implications of *transactions* involving human bodies and *bodily material* in medical treatment and research.

2. To consider, with reference to different forms and purposes of donation or volunteering, what limits there should be, if any, on the promotion of donation or volunteering, including consideration of:

    a. the role of payment and any other form of remuneration or exchange;
    b. the role of consent;
    c. the question of subsequent use, ownership and control of donated materials;
    d. the role of those acting as intermediaries between donors and recipients; and
    e. the cultural and international perspectives, including regulatory differences.

3. To draft a Report and make recommendations on these issues.

Contents

This Consultation Paper contains an introduction and six separate sections of questions, each accompanied by some background explanatory material. Please feel free to answer as many, or as few, questions as you wish, and to take them in any order you wish. Italicised words are included the glossary where more detailed information is provided.

Questions are addressed to 'you' either as an individual or as an organisation, and respondents should feel free to interpret them in the way that fits best with their own experience or knowledge. The aim of this consultation is not to gather quantitative data about opinions, but rather to collate as many views and approaches to these issues as possible, in order to inform the Working Party's own deliberations. Please therefore feel free to respond with your own personal views, with any commentary on the range of views of which you are aware, or with your organisation's policy on the issue at hand, as appropriate.

If you have personal experiences which are relevant to the issues being considered during this consultation, the Working Party would be pleased to receive your views in the "Any other issues" section, either in addition to the consultation questions or as an alternative to them.

Introduction

The *Nuffield Council on Bioethics* has established a Working Party to examine the ethical issues that arise in connection with a person's decision to 'donate' some part of their body (including whole organs, eggs and sperm, blood, and other *bodily material* such as bone, skin, heart valves and corneas) or to 'volunteer their body' through participation in *'first-in-human'* clinical trials of new medicines.

The Nuffield Council first discussed some of these issues in its 1995 report 'Human tissue: ethical and legal issues', which considered ethical concerns across a wide range of possible uses of human bodily material. Fifteen years later, after considerable scientific, social and legal change, the Council feels that it is timely to return to this field, focussing specifically on the ethical issues that arise for the individuals concerned, when a person comes to make his or her decision to provide bodily material or volunteer for first-in-human research. In particular, it is interested in exploring the regulatory differences between providing eggs or sperm, providing other forms of bodily material, and volunteering for first-in-human research, and in considering whether or not such regulatory differences can be justified. Any form of human bodily material that may be provided for the benefit of others in medicine or research is potentially within the remit of the enquiry, although clearly some forms of material, or the circumstances in which they are provided, will raise more pressing ethical questions than others. The primary focus of the enquiry is within the United Kingdom, although some aspects will inevitably cross national boundaries.

Factors being considered include:

- What degree of encouragement to provide human bodily material or volunteer in a first-in-human trial is ethically acceptable? Is there a point at which it must be accepted that supply cannot meet demand?
- What is required for a valid consent to provide bodily material or to volunteer? What might undermine a person's consent?
- What future control can the *'donor'* or *'volunteer'* reasonably exert, for example over later uses of donated material?
- 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?
- 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?

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.

The Working Party would like to hear from anyone who has an interest in this field, whether professional or personal. This could include, among others, professional organisations and individuals working in this area, specialist interest or support groups, academics, individuals who have provided some part of their body or volunteered in a first-in-human trial, individuals whose family members have provided bodily material after death, and individuals who have benefited, or are hoping to benefit, from donated bodily material.

This consultation document provides background information and raises questions on some of the issues the Working Party is currently considering. You can respond to as many or as few questions as you wish, but please feel free also to highlight any issues, connected with our Terms of Reference, that are not covered in this consultation paper.

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.

1. Nature of human bodily material and first-in-human trials

Human bodily material

A wide range of human *bodily material* may be provided by individuals for the benefit of others, either for use in medical treatment or for *research*. In the UK, these materials include:

- *Blood*, for transfusion and many other medical purposes such as treatment of anaemia, leukaemia and haemophilia. Donated blood may be used for research if not needed for treatment, and samples of blood will often be taken during medical investigations or as part of a clinical trial or other research project
- Whole organs, such as kidneys, heart, liver, lungs, pancreas and the small bowel for transplantation (or research if not suitable for transplantation)
- Partial organs, such as the lobe of a liver for transplantation (or research)
- *'Tissue'* such as corneas, skin, bone, heart valves, tendons, cartilage, bone marrow and adult *stem cells* for transplantation or research
- Sperm, for use in infertility treatment or research
- Eggs, for use in infertility treatment or research
- Embryos, for use in infertility treatment, for example where neither partner can produce viable *gametes*, or research
- Products of conception such as aborted foetal material and embryonic stem cells for research and potentially treatment in the future.
- The whole body after death, for education, training or research.

Depending on its type, bodily material can be provided by living *donors* or after death. Living donors provide blood and bone-marrow, and are the only legal source of sperm and eggs in the UK (although donation after death is technically possible). Historically organs and tissues for transplantation and research have been obtained after death. However, the use of living whole organ donors is increasing rapidly, and in 2008-09 the number of living donors slightly exceeded the number of deceased organ donors in the UK. At present the organs provided by living donors are primarily kidneys but developments in surgical techniques have made partial donations of organs such as the liver and lung possible. While tissues are primarily donated after death, some forms of tissue such as bone may also be provided by living donors undergoing hip replacement surgery.

Other distinctions that can be made between various different types of bodily material include:

- Material that naturally renews itself, such as blood and sperm
- *Non-regenerative material*, such as whole organs
- Reproductive material that may result in the birth of a child genetically related to the person providing the material

- Material that is removed from the body in the course of another procedure, such as material excised during an operation and cord blood or amniotic membrane which may be retrieved at childbirth. Such materials have often been treated as 'waste' but may have value both for the person from whose body they have come and to others.

Questions

1. Are there any additional types of human bodily material that could raise ethical concerns?
2. Should any particular type(s) of human bodily material be singled out as 'special' in some way?
3. Are there significant differences between providing human bodily material during life and after death?
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.

Participation in first-in-human trials

First-in-human trials are used to test the safety of new medicines on volunteers who do not expect to gain any medical benefit from the trial. In a sense, the volunteer 'provides' or 'loans' their body for a short period so that researchers can find out how a new medicine acts on the human body. Where possible, 'healthy volunteers' are used; however, for safety reasons, it may sometimes only be possible to test the new medicine on a patient with the particular condition being targeted.

In this consultation, we are interested in exploring whether meaningful parallels can be drawn between those who provide bodily material for medical treatment and research, and those who provide their bodies on a temporary basis for experimentation with no expectation of personal health benefit.

Question

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?

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.

2. Purposes of providing bodily material/volunteering in a trial

Human bodily material may be provided both for medical treatment and for *research*. However, further distinctions may be made as to the purpose for which it is to be used. Treatment using donated material may be:

- **Life-saving** (for example blood used to replace blood lost in accidents, surgery or childbirth, or skin used to treat very serious burns)
- **Life-prolonging** (for example a kidney transplant)
- **Life-enhancing** (for example a corneal transplant, restoring sight)
- **Life-creating** (for example use of donated egg, sperm or embryo to enable an infertile woman/couple to have a child)

Similar distinctions may potentially be drawn with respect to volunteering for first-in-human research on new medicines, and in the use of bodily materials for research, depending on the therapeutic aims of the medicine being tested or the research.

Further distinctions may be made in terms of the specificity and timing of the use. The provision of bodily material may be:

- **Directed in some way**, where the person providing the material does so on the basis that it will benefit a particular individual or group (for example living organ donation or the provision of tissue for genetic testing to benefit relatives); or
- **Non-directed**, where the person providing the material has no control over who will benefit from the donation (for example most organ donation after death).

The provision of bodily material for research may be:

- **For immediate use**, so that the person providing the tissue can be given information about the proposed research project; or
- **For future and hence unspecified purposes**, for example donations to *UK Biobank*. Material provided for a specified use may also turn out later to have a value for research purposes that could not be predicted at the time the material was provided.

Finally, bodily materials for either treatment or research may be:

- **Used in their existing form**, such as organs and gametes for treatment
- '**Processed**' or 'transformed' in some way, for example tissue-engineered products incorporating human skin, or the creation of a cell-line
- **Used non-commercially within the health system**, such as whole organs donated after death

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.

- Potentially used **within a commercial environment,** such as tissue provided to tissue banks or donated gametes used in private fertility clinics.

Questions

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

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

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)*

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.

3. Ethical values at stake

The use of bodily material in treatment and research, and the recruitment of human volunteers in first-in-human trials, generate a number of (sometimes competing) ethical concerns. These concerns become particularly acute where there is a potential shortfall in donors/volunteers in some areas, and hence the question arises as to how far public or private bodies may go in actively encouraging, or indeed incentivising, people to provide their bodily material or to volunteer for a trial. They are also central in considering issues around control and ownership of our bodies and material deriving from our bodies, and in determining the role of consent. A number of relevant ethical values are listed below, with links to a more detailed account of each in the glossary.

***Altruism**:* the emphasis on donation as a selfless *gift* to others without expectation of remuneration. Altruistic giving may be to strangers, or may take place within the context of family or other relationships

***Autonomy*:** widely understood as underpinning our entitlement to control our own bodies, because they are 'ours'

***Dignity*:** encapsulating ideas of the special status of the human body and associated with concerns that putting a price on any part of a human body would 'commodify' it in a way incompatible with its unique status

***Justice*:** concerned with a 'fair' distribution of benefits and burdens within or between societies, and also with notions of 'fair recompense' for the donor or volunteer

***Maximising health and welfare*:** aiming to achieve the best possible outcomes for the greatest number, minimising harm and maximising benefit overall

***Reciprocity*:** providing benefits or services to another as part of a mutual exchange

***Solidarity*:** the idea that 'we're all in this together', with a recognition of mutual obligations and mutual support within a community based on geography or on shared interests.

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.

Questions

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

10. How should these values be prioritised, or balanced against each other? Is there one value that should 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? Does the type or purpose of bodily material or medicine being tested make a difference?

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?

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?

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.

4. Responding to demand

Supply and demand

There is constant pressure within the UK to meet the demand for some types of human bodily material. Demand significantly exceeds supply both for whole *organs* for transplantation and for *gametes/embryos* for infertility treatment and research; the gap between supply and demand is particularly acute for those of non-white ethnic origin. Supplies of *blood* are under constant pressure, and while supplies of *tissue* for research and treatment are usually adequate, short-term shortages of particular forms of tissue for treatment can arise in emergencies. Commercial researchers may also at times experience difficulties in accessing material donated within the public sector. Transplant and fertility *'tourism'*, where patients go to other countries where organs and gametes are more readily available to them, is widely reported. Some form of payment is generally assumed to be necessary in order to recruit the requisite number of volunteers to participate in first-in-human trials.

Question

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

Current regulatory framework

The current law in the UK permits different forms of incentive, compensation or recognition to encourage people to provide different forms of bodily material or participate in a first-in-human trial:

- Blood, organs and tissue for transplantation: no direct payments permitted. Living organ donors can claim directly incurred *expenses*, including loss of earnings, as can bone marrow donors. Regular blood donors receive awards, such as colour-coded donor cards, key fobs and certificates in recognition of their contribution.
- Gametes and embryos: no direct payments permitted. Donors may recoup *expenses*, although compensation for lost earnings is capped. Free or reduced-cost fertility treatment may be offered in return for the donation of eggs either for others' treatment or for research.
- 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.

Question

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?

Increasing supply

Recent UK initiatives to increase the supply of bodily material, particularly organs, have included:

- Improvements in *transplant infrastructure* to maximise donations after death
- Increased public awareness, for example through prominent campaigns
- The introduction of *'paired'* or *'pooled'* living organ donations
- The introduction of 'stranger' living organ donation, where donors give a kidney to a stranger in a similar fashion to blood donation
- Making greater use of the organs that are already available, for example through the use of *'extended criteria'* donors.
- Permission, on a case-by-case basis, for the creation of *'saviour siblings'* whose cord blood can be harvested to treat an older sibling suffering from a serious inherited disorder.

Many **other approaches** have been put forward as to the best way to respond to shortages in various forms of human bodily material, and the best known of these are outlined below:

- Greater use of *non-financial tokens of gratitude* such as private letters of thanks or inclusion in public memorials

- Use of *'non-cash' incentives* with some (small) monetary value, such as T-shirts, mugs and vouchers, for example to encourage wider participation in blood donation

- Various forms of *financial incentive* for gamete donors and living organ donors. Such payments could range from more generous compensation arrangements for *expenses* and inconvenience, through a regulated system for selling organs/gametes at non-market rates to a governmental organisation, to a fully-fledged free market

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

- Introduction of *'opt-out'* or *mandated choice* systems for organ donation after death

- Introduction of some form of *'benefit sharing'*, under which those providing bodily material would enjoy non-financial benefits linked with their donation such as priority for an organ if in the future they come to need one

- Improved systems to make it easier for researchers to access blood or tissue samples 'left-over' after diagnostic procedures or treatment

- Expanding further the circumstances in which the provision of bodily material is permitted, for example by rescinding the current ban on the use of *eggs* (see *gametes*) from deceased donors, or facilitating organ donation from people who die from a cardiac arrest outside hospital (so-called uncontrolled *donation after cardiac death*).

Questions

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?

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

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

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?

* *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*

Alternatives to increasing supply

The approaches described above all focus on how people may be motivated or incentivised to provide bodily material, hence increasing supply. New scientific developments, on the other hand, may in the future reduce, or replace altogether, some uses of bodily material, hence potentially reducing demand. Examples include:

- Technical improvements in egg freezing that may make it possible in the future for women to use their own eggs when they would otherwise have had to contemplate using donated eggs
- Mechanical alternatives to donated organs, such as '*ventricular assist device*' technology used instead of a heart transplant
- Development of artificial tissues for transplantation, such as *artificial corneas*.

It should, however, be noted that the relationship between supply and demand for human bodily material is a complex one, and that the development of alternatives may lead to more people overall being treated, rather than necessarily reducing demand. Those currently considered 'too ill' to be placed on a transplantation list, for example, may still have the potential to benefit if an organ becomes available; and further developments in medical science may lead to an increasing number of transplants becoming clinically appropriate.

Question

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?

5. The role of consent

Valid consent

The consent of participants in both medical research and medical procedures is a standard ethical and legal requirement around the world. In the UK, the common law governs both consent to treatment (which legally would encompass consent to the procedures involved in providing bodily material as a living donor) and consent to research participation. The consent requirements for the storage and use of material from living donors, and for the removal, storage and use of bodily material after death, are set out in the Human Tissue Act 2004 which governs England, Wales and Northern Ireland. The equivalent legislation in Scotland is found in the Human Tissue (Scotland) Act, where the term 'authorisation' rather than consent is used.

Both common law and the Code of Practice on consent issued under the Human Tissue Act require that, for consent to be *valid*, the person giving consent must:

- have the legal capacity to make this particular decision;
- have been provided with information about the nature and purpose of the procedure; and
- be acting voluntarily, without pressure or undue influence being exerted.

There is controversy as to whether the offer of any significant incentive – whether in the form of direct cash payments or indirect financial benefits such as free or reduced fees for IVF treatment – could act as a form of '*undue influence*' on the person concerned, thus invalidating their consent. On the one hand, it is suggested that such incentives may encourage people in need of money to accept risks that they would otherwise have rejected; on the other hand, it is argued that an incentive simply increases the range of options open to the person, and that it cannot be coercive to offer them the choice.

Concerns about potential coercion may also arise in the family context, where there may be strong, if often hidden, pressures on one family member to provide bodily material such as an organ or bone marrow for another. It may be very difficult to distinguish between such coercion, and circumstances where a family member voluntarily donates through a sense of duty or responsibility within the family.

Questions

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

Consent for future unknown ('secondary') uses of bodily material

When a person gives their consent to the use of their bodily material for research purposes, this may be a 'specific' consent for a particular research project or a 'generic' consent authorising its use in any (ethically approved) research project in the future. Generic consent is preferred by researchers because of the possibility that the bodily material may have valuable research uses that cannot be predicted at the time the material was provided and the difficulties involved in tracing people potentially many years later.

If generic consent to research is not given at the time the person provides the material, then researchers will usually only be able to use it in a new research project if they are able to contact the person who provided the material, and ask for their consent again. However, the Human Tissue Act makes an exception to the general consent principle, allowing additional future research use of bodily material from a living donor without explicit consent if:

- the researcher is not in a position to identify the person from whom the material came; and
- a Research Ethics Committee has approved the research proposal, in the knowledge that explicit consent to this use of the material has not been obtained.

'Residual' blood or tissue left over from diagnostic procedures or surgery may similarly be used for research without explicit consent if a Research Ethics Committee approves and the researcher cannot identify the person from whom the material came.

Question

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?

Role of families: living donation

Where an adult has the capacity to decide for themselves whether or not to provide some form of bodily material whilst living, only that adult can provide consent. In England, Wales and Northern Ireland, a child of sufficient maturity and understanding can provide valid consent to the donation, storage and use of bodily material such as bone-marrow, although court approval is additionally required for the donation of an organ or part organ. If the child is not legally 'competent' in this way, or prefers not to make the decision, a person with parental responsibility may do so, on the basis of the child's best interests.

An adult who lacks capacity to make a decision to provide bodily material for use in medical treatment may only do so if it is judged to be in the person's best interests, and court approval must be sought for the donation of solid organs, bone marrow or peripheral blood stem cells. Participation in research (which may include providing bodily material such as blood samples) is only lawful if the research has the capacity to benefit that person, or where the risk involved is 'negligible'.

In Scotland, a 'child' is defined as under 16 years of age and young people of 16 and above therefore count as adults. Children under 16 and adults who lack capacity to decide for themselves are not permitted to donate organs or part organs as living donors, unless the organ or part organ is being removed as part of their own treatment. However, they may donate bone marrow or peripheral blood stem cells subject to a number of protections.

Question

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?

Role of families: donation after death

Under the Human Tissue Act (which governs England, Wales and Northern Ireland), an adult may consent in advance to the removal and use of some or any part of their body after death. Family members have no right in law to override this decision and refuse to permit donation after the person's death, although in practice hospitals are very unlikely to remove material in the face of family opposition. Adults may also nominate a person to make the decision about donation on their behalf. If the deceased person has neither given consent nor nominated a representative during their lifetime, then a person in a *'qualifying relationship'* with him or her at death can be asked to decide.

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.

Children and young people under 18 who have sufficient maturity and understanding may give advance consent to the removal of bodily material after death in the same way as an adult, although the Human Tissue Act Code of Practice emphasises the importance of discussing the child's decision with the family. Otherwise, those with parental responsibility will be asked to decide. In Scotland, children are entitled to give their own authorisation to the use of their bodily material after death from the age of 12.

Question

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?

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.

6. Ownership and control

Property rights

There is a long legal tradition in the UK and many other countries that there can generally be *no property* rights in a human body, living or dead. Our rights in connection with our own bodies are not legally those of 'ownership', and we cannot be owned by others. However, the courts have in certain circumstances been willing to recognise exceptions to this rule, particularly in relation to body parts. It is now well established that the 'application of human skill' may turn a body part into property: preserved human body parts used for training surgeons, for example, have been held to be property and hence protected by the law of theft.

In 2009, the Court of Appeal extended this exception further, by holding that sperm was capable of being the property of the men who had produced it, in circumstances where it had been frozen on behalf of men undergoing chemotherapy (in order to protect their fertility) and then by error destroyed. The Court made clear that it did not base its finding on the fact that human skill had been used to freeze the sperm, commenting that "developments in medical science now require a re-analysis of the common law's treatment of and approach to the issue of ownership of parts or products of a living human body".

Issues of property ownership are clearly closely interlinked with questions of financial gain and concerns about the 'commodification' of human body parts. Once human bodily material has been transformed through the application of skill, third parties may sometimes be able to use it for commercial purposes. The individual providing the material, however, is not necessarily entitled to benefit commercially.

Questions

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?

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

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?

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.

Control

Although courts and governments have been reluctant to recognise any general form of property ownership in the human body, there is a widespread acknowledgment of the importance people place on being able to control or dispose of their own bodies. In medical treatment and research during life, recognition of a person's right to control their own body is expressed through the requirements for *valid consent*. Public anger about the retention of organs at Alder Hey Hospital and Bristol Royal Infirmary demonstrated the strength of feeling also attached to the desire for individuals and their families to be able to determine what happens to human bodies after death. The regulatory frameworks introduced by both the Human Fertilisation and Embryology Act and the Human Tissue Act are based on a system of consent, thus providing some degree of control but without granting any legal right of ownership. There is, however, no absolute right of control over one's own body: the state and/or public opinion may put limits on how people use their bodies, for example through the regulation of working hours or prohibition on certain drugs.

The degree of control that people who provide bodily material may exercise over its use often depends on the type of material. Gamete donors, for example, are given the opportunity on the consent form of specifying restrictions on the use of their donation. So, for example, a woman could donate specifically to a sister or friend. Living donors of organs, and of tissues such as bone marrow and cord blood, may also specify the person who will benefit from their donation, but only in exceptional cases may any such conditions be placed on organs donated after death. Those providing bodily material of any kind may also exert a limited degree of control by choosing to give consent to one kind of usage and not another, for example by consenting to use for treatment purposes but not for research. They may also withdraw their consent at any time before the material is used.

Question

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.

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.

7. Any other issues

Question

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

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.

Glossary

Altruism. The basis of blood and organ donation in the UK has, from the start, been presented as one of altruism, understood as a selfless gift to others without expectation of remuneration.[1] The widespread support for this model for donation is found in descriptions such as 'giving the gift of life', and contrasts with the common portrayal of those paid to participate in first-in-human clinical trials as 'human guinea-pigs'.[2] A strong emphasis on altruism is found in the EU Tissues and Cells Directive which states firmly that "as a matter of principle, tissue and cell application programmes should be founded on the philosophy of voluntary and unpaid donation, anonymity of both donor and recipient, altruism of the donor and solidarity between donor and recipient."[3] Some argue, however, that a model of individual altruism no longer sits easily in the more commercial world of modern health care.[4] Others express concern that the traditional altruistic model can often be subject to hidden coercive pressures, as when patients on a transplant list might 'expect' a suitable relative to donate an organ to help them.[5]

Artificial corneas: Corneal substitutes are being developed both in response to the shortage of donated corneas, and with the aim of overcoming clinical problems involved in the use of donated material such as rejection by the immune system.[6]

Autonomy is widely understood as underpinning our entitlement to control our own bodies, because they are 'ours'. Respect for autonomy is shown primarily through the importance placed on consent: valid consent must be given before bodily material may be taken, and before a person participates in a first-in-human trial. Concerns about coercion and 'undue inducement' undermining valid consent similarly reflect the importance attached to ensuring that decisions about a person's body are freely and autonomously made by the person concerned. More controversially, it may also be argued that respect for autonomy should entail permitting people to do what they wish with their own bodies, including selling their own bodily material as a commercial transaction.[7]

---

1 Titmuss RM (1970) *The gift relationship: from human blood to social policy* (London: Allen and Unwin).

2 See, for example, Mandeville K (2006) My life as a guinea pig *British Medical Journal* **332**: 735.

3 European Union Tissues and Cells Directive, Directive 2004/23/EC, recital 18, available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:102:0048:0058:EN:PDF.

4 Busby H (2006) Biobanks, bioethics and concepts of donated blood in the UK *Sociology of Health & Illness* **28(6)**: 850–65.

5 Scheper-Hughes N (2007) The tyranny of the gift: sacrificial violence in living donor transplants *American Journal of Transplantation* **7**: 507–11.

6 Griffith M, Jackson WB, Lagali N *et al.* (2009) Artificial corneas: a regenerative medicine approach *Eye* **23**: 1985–9.

7 See, for example, the discussion in Radcliffe-Richards J, Daar AS, Guttmann RD *et al*. (1998) The case for allowing kidney sales *Lancet* **351:** 1950–2.

Benefit sharing: One example of benefit-sharing in research is the approach taken by the Human Genome Organisation (HUGO) which prohibits "undue inducement through compensation" for participants in genetic research but argues that the interests of justice compel researchers to share benefits of other kinds, including education, training and health care provision, with the subjects of their research.[8] One possible 'benefit' that could be offered to those committing themselves to donating after death could be the promise of priority for an organ transplant should they ever find themselves on a transplant waiting list.[9]

Blood: A national system for blood donation has been in place in the United Kingdom since 1946, with approximately 1.4 million registered donors in England and North Wales donating through NHS Blood and Transplant.[10] Supplies of blood are often under pressure, and while increased efficiency in hospitals has reduced the demand for blood supplies, in recent years the number of donors has been falling at a faster rate.[11] Whole blood is used relatively rarely, for cases of really severe blood loss, and hence donated blood is usually separated into its individual components: red cells, platelets and plasma.

Bodily material: In this consultation document, we use the term 'bodily material' to include all forms of human biological material that can be donated for use in medicine and research, from individual cells to solid organs. See also **Tissue**.

Dignity. The concept of the inherent dignity, or special status, of the human body is usually traced back to the work of Immanuel Kant.[12] In a Kantian view, dignity and price are essentially mutually incompatible: the maintenance of human dignity requires human beings to be beyond negotiable price. Putting a price on a human being, or on part of their body, would be to give it a relative value, while human beings are of "incomparable ethical worth".[13] If this view of human dignity is accepted, then any form of financial payment, or 'commodification' of bodies or body parts would constitute a violation of human dignity, even if the person

---

8 Knoppers BM, Chadwick R, Takebe H *et al.* (2000) *Statement on benefit sharing* (HUGO Ethics Committee: Vancouver), available at: http://www.hugo-international.org/img/benefit_sharing_2000.pdf.

9 Landry DW (2006) Voluntary reciprocal altruism: a novel strategy to encourage deceased organ donation *Kidney International* **69**: 957–9; Israel has just announced a scheme on this basis: Lavee J, Ashkenazi T, Gurman G and Steinberg D (2009) A new law for allocation of donor organs in Israel *Lancet* **375**: 1131–3.

10 NHS Blood and Transplant news release 26 May 2009, available at: https://safe.blood.co.uk/PressRelease/NHSBT%20Annual%20Activity%20Eng%20and%20NW%20FINAL%2026%20May%202009%20(2).pdf.

11 NHS Blood and Transport (2009) *Strategic plan 2009/12* (London: NHS Blood and Transplant), p3, available at: http://www.nhsbt.nhs.uk/downloads/board_papers/mar09/strategic_plan_09_13.pdf .

12 See, for example, Cohen CB (1999) Selling bits and pieces of humans to make babies: the gift of the magi revisited *Journal of Medicine and Philosophy* **24(3)**: 288–306; Waldby and Mitchell (2006) *Tissue economies: blood, organs and cell lines in late capitalism* (Durham, NC: Duke University Press).

13 Cohen CB (1999) Selling bits and pieces of humans to make babies: the gift of the magi revisited *Journal of Medicine and Philosophy* **24(3)**: 288–306, at 292.

concerned did not personally feel in any way degraded. Such a view is strongly challenged by some who argue that "degradation very much depends on one's own perception of what is degrading".[14]

Donation after cardiac death (DCD) donors (also known as non-heart-beating donors): In the UK, donation after cardiac death usually takes place where death is established by the irreversible cessation of the heart, after the withdrawal of life-sustaining cardio-respiratory support on the basis that this support is no longer in the patient's best interests.[15] However, 'uncontrolled' donation after cardiac death, where the donor dies outside hospital of a heart attack, is also possible, despite the inevitable delays before organs may be obtained. French researchers recently suggested that, for kidneys, such donors could provide a "significant proportion of the functional organs provided for transplant".[16]

Donors: those who provide human bodily material for use in medical treatment or research. We use the term in this document to refer to anyone (alive or deceased) providing human bodily material, whether or not they receive any form of compensation for doing so. See also **Gift.**

Expenses: In the UK, living organ donors can claim expenses directly incurred as a result of the donation procedure, including loss of earnings due to time off work.[17] Bone marrow donors may similarly be compensated for lost earnings if they need to take time off work.[18] Gamete and embryo donors may also claim expenses directly incurred, including lost earnings that are directly related to the donation; however compensation for lost earnings is restricted to a maximum payment of £61.28 per day with a 'cap' of £250 per course of sperm donation or cycle of egg donation.[19] Recognising the current difficulties in recruiting egg donors, the Human Fertilisation and Embryology Authority announced in

---

14 Daar AS (1998) Paid organ donation – the Grey basket concept *Journal of Medical Ethics* **24**: 365–8, at 365.

15 Department of Health (2009) *Legal issues relevant to non-heartbeating organ donation* (London: Department of Health), paragraph 1.3, available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_108825.

16 See, for example, Richards L (2009) Kidneys from non-heart-beating donors *Nature Reviews Nephrology* **5**: 666.

17 Human Tissue Authority (2009) *Code of practice 2* (London: Human Tissue Authority), paragraph 42, available at: http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code2donationoforgans.cfm?FaArea1=customwidgets.content_view_1&cit_id=673&cit_parent_cit_id=669; see also http://www.dh.gov.uk/en/Healthcare/Longtermconditions/Vascular/Renal/RenalInformation/DH_4069293.

18 See the NHS Blood and Transplant website at: http://www.nhsbt.nhs.uk/bonemarrow/qa/.

19 These policies are laid out in the HFEA's Directions (Gamete and Embryo Donation 0001) which have statutory force under Section 12(1)(e) of the Human Fertilisation and Embryology Act 1990 (as amended), available at: http://www.hfea.gov.uk/docs/2009-06-03_GENERAL_DIRECTIONS_0001_Gamete_and_Embryo_donation_-_approved.pdf.

December 2009 that it would be reviewing the issue of "reimbursement and compensation" of egg donors, although within the context of the European Tissues and Cells Directive which limits remuneration to "making good expenses and inconveniences to the donation."[20] While the terms 'expenses' and 'reimbursement' will generally be understood to refer only to actual financial losses incurred, 'compensation' for 'inconvenience' is clearly a more elastic concept (see **Financial incentives**).

Extended criteria donations: One approach to meeting the shortfall in donated kidneys, for example, has been to employ 'extended criteria' for accepting offered organs, making it possible to use kidneys removed after death which are of poorer quality, but still acceptable to use.

Financial incentives: Proposals for financial incentives range from small cash rewards (which might equally be described as compensation for inconvenience – see **Expenses** above) to a fully-fledged free market in human bodily material. Objections to such incentives are made both on principled and pragmatic grounds, with some concerned about the 'commodification' of the human body, while others are anxious that such a market system would lead to the exploitation of the poor and vulnerable in both high and low income countries (see **Tourism**). The apparent inconsistency of permitting payment for clinical trial participants, but not for organ or gamete donors has been noted by a number of commentators with comparisons particularly being drawn between the role of paid healthy volunteers and that of women undergoing invasive surgery in order to donate eggs for research who receive only minimal expenses.[21] See also **Justice**.

First-in-human trials: 'Phase 1' or 'first-in-human' clinical trials (also known as 'first-in-man' or 'healthy volunteer' trials) are used to test the safety of new medicines in humans, after laboratory and animal testing and before testing the effectiveness of the medicine in patients. Participants are usually 'healthy volunteers' although some types of new medicine may only be tested in patients with a particular condition. According to the Medicines and Healthcare Products Regulatory Agency (MHRA), which oversees the safety of clinical trials in the UK, 235 applications for new trials using healthy volunteers were made in 2009.[22]

Volunteers do not expect to receive any medical benefit from the medicine being tested, and are paid for their participation. Payments vary according to the nature

---

20 HFEA news release 9 December 2009, available at: http://www.hfea.gov.uk/5666.html.

21 See, for example, the discussion in Ahuja KK and Simons EG (1996) Anonymous egg donation and dignity *Human Reproduction* **11(6)**: 1151–4; Roff SR (2006) Thinking the unthinkable: selling kidneys *British Medical Journal* **333**: 51; and Hyun I (2006) Fair payment or undue inducement? *Nature* **442**: 629–30.

22 MHRA (2009) *Clinical trial assessment performance: healthy volunteer trials* (London: MHRA), available at: http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Clinicaltrials/UKclinicaltrialauthorisationassessmentperformance/index.htm.

of the trial including the duration of the trial, the lifestyle restrictions, and potential discomfort involved. The most recent guidelines on phase 1 clinical trials from the Association of the British Pharmaceutical Industry (ABPI) recommend a payment model based on the current minimum wage and emphasise that payment must never be related to risk.[23] While a study of 65 volunteers taking part in first-in-human trials in the UK identified payments ranging between £185 and £750,[24] much higher payments have been reported in some cases.[25]

Gametes (eggs and sperm): It is estimated that around 2,000 babies are born each year in the UK as a result of donated eggs, sperm or embryos, although there is no breakdown of this figure.[26] Potential recipients are likely to wait over a year for suitable donor eggs and the gap between supply and demand is particularly acute for those of non-white ethnic origin.[27] Eggs and sperm may only be provided by live donors; although it is possible to retrieve eggs after death or from aborted foetuses, this is currently banned in the UK.[28]

Gift: A donation made without formal expectation of return (see **Altruism**). Once a gift has been handed over it ceases to belong to the donor. Thus a blood sample given for research purposes may be technically designated a gift, the donor thereby giving up any claim to any benefit that might result from the research in the long term.

Justice is concerned with a 'fair' distribution of benefits and burdens within or between societies. Issues of justice arise in at least two distinct contexts in donation and volunteering. Firstly, there is the concern that any form of commercial market for tissue may induce primarily the poorest and most vulnerable members of society into becoming donors, with the main recipients being the better-off. This could occur both *within* individual countries (low, middle and high income countries alike) and also lead to inhabitants of lower income countries becoming the main source of organs and gametes – "donor nations"[29] – for the inhabitants of wealthier nations. Similar concerns arise in connection

---

23 Association of the British Pharmaceutical Industry (2007) *Guidelines for phase 1 clinical trials* (London: Association of the British Pharmaceutical Industry), available at: http://www.abpi.org.uk/publications/pdfs/phase1_guidelines.pdf.

24 Ferguson PR (2008) Clinical trials and healthy volunteers *Medical Law Review* **16(1)**: 23–51.

25 See, for example, Brazier M (2008) Exploitation and enrichment: the paradox of medical experimentation *Journal of Medical Ethics* **34**: 180–3 which cites the figure of £2,000 for participating in the Northwick Park trial.

26 Statistics taken from the HFEA website, available at: http://www.hfea.gov.uk/3415.html. There is no breakdown as to what proportion of this total is due to use of each specific type of donated material (e.g. how many babies are born as a result of fertility treatment using donated sperm compared with the number resulting from treatments involving donated eggs).

27 HFEA (2004) *Sperm, egg and embryo donation (SEED) policy review: findings of the clinical survey*, available at: http://www.hfea.gov.uk/docs/Clinics_survey_Seed_review.pdf.

28 It has, however, been suggested that this ban could be reconsidered in order to increase the supply of donor eggs: see Johnson MH (1999) The medical ethics of paid egg sharing in the UK *Human Reproduction* **14(7)**: 1912–8.

29 Friedman EA and Friedman AL (2006) Payment for donor kidneys: pros and cons *Kidney International* **69**: 960–2.

with participation in first-in-human trials, especially where those volunteering for such research have poor access to healthcare and are unlikely to access the resulting benefits. Secondly, and from a very different perspective, there is the question of what constitutes 'fair recompense' to the donor or volunteer, especially where others (intermediaries such as fertility clinics or tissue banks) potentially stand to gain commercially.

Mandated choice: A system requiring everyone to register in advance whether they are, or are not, willing to provide bodily material for treatment or research after their death. In 2009, the Ethics Committee of the Royal College of Physicians proposed adopting such a scheme, with a third option of 'Ask my family at the time'.[30]

Maximising health and welfare: An ethical approach that prioritises the achievement of the best possible outcome for the greatest number, minimising harm and maximising benefit overall. One argument that is sometimes made in favour of an 'opt-out' system (where organs are routinely taken after death unless the person has explicitly objected) is that the good to those able to benefit from treatment and research exceeds the harm of the interference with autonomy. A similar argument could be made for a moral duty to participate in research.[31] On the other hand, arguments based on the maximisation of health and welfare may be used *against* the use of commercial markets in human tissue and the use of payment in first-in-human trials because of concerns about the creation of an underground 'shadow economy' of exploited and vulnerable members of society.[32]

No property rule: The Court of Appeal case of *Yearworth and others v North Bristol NHS Trust* [2009] EWCA Civ 37 summarises the history of the legal principle that there can be no property in either a living body or a corpse, with the exception of cases where "they have acquired different attributes by virtue of the application of skill" (*R v Kelly and Lindsay* [1999] QB 621). In the case of *Yearworth* (which considered the possibility that frozen sperm, destroyed as a result of NHS errors, could constitute property), the Court of Appeal declined to base its decision on the "application of skill" exception, arguing that a "broader basis" was required. It found that, in this particular case, the sperm should constitute the men's property, given both that they had generated it, with the sole purpose of using it later for their own benefit, and that the consent requirements

---

30 Laurance J (2009) Change law on organ donation, doctors say, *Independent*, 2 November; Saunders J (2010) Bodies, organs and saving lives: the alternatives *Clinical Medicine* **10(1)**: 26–9.

31 Harris J (2003) Organ procurement: dead interests, living needs *Journal of Medical Ethics* **29**: 130–4; Harris J (2005) Scientific research is a moral duty *Journal of Medical Ethics* **31**: 242–8.

32 See, for example, Elliott C and Abadie R (2008) Exploiting a research underclass in phase 1 clinical trials *New England Journal of Medicine* **258**: 2316–7; Chapman J (2008) Should we pay donors to increase the supply of organs for transplantation? No *British Medical Journal* **342**: 1343.

within the Human Fertilisation and Embryology Act included such "fundamental features of ownership" as the power to order at any time the destruction of the sperm.

'Non-cash' incentives: Items with some monetary value, such as T-shirts, mugs and vouchers, have been suggested in the context of blood donation, the aim being to attract donors from across the income spectrum and not specifically those in need of money for daily living expenses.[33] See also **Financial incentives**.

Non-financial tokens of gratitude: The Organ Donation Taskforce highlighted a range of possible tokens to recognise both living donation and donation after death, and commented: "The Taskforce considered options such as a memorial garden, an eternal flame and a web-based register. However, it felt that it did not have the evidence or expertise to make specific detailed recommendations, although it felt strongly that appropriate recognition of donation should be established and provided."[34]

Non-regenerative material: Human bodily material that does not naturally renew itself and which will hence not be naturally replaced by the body if donated.

Nuffield Council on Bioethics: The Council examines ethical issues raised by new developments in biological and medical research. It is an independent body, funded jointly by the Nuffield Foundation, the Medical Research Council and the Wellcome Trust. It works by considering topics in depth, publishing reports on its findings and making recommendations to policy makers.

Opt-out approach to organ donation: The current legal position in the UK requires consent to be given, either by the donor before death or by their family after death, before organs may be taken from a deceased person. The proposal that this system should be replaced by an 'opt-out' system, in which removal of organs after death would be routine unless the person had logged a specific objection in advance, has long been debated within the UK and elsewhere.[35] In 2008 the Organ Donation Taskforce was specifically asked to consider whether it would recommend such a system in the UK, and rejected the proposal at the present time.[36]

---

[33] See discussion in Buyx AM (2009) Blood donation, payment and non-cash incentives: classical questions drawing renewed interest *Transfusion Medicine and Hemotherapy* **36**: 329–39.

[34] Department of Health (2008) *Organs for transplants: a report from the Organ Donation Taskforce* (London: Department of Health), paragraph 4.46, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_082120.pdf.

[35] English V and Sommerville A (2003) Presumed consent for organ transplantation: a dead issue after Alder Hey? *Journal of Medical Ethics* **29**: 147–52.

[36] Organ Donation Taskforce (2008) *The potential impact of an opt out system for organ donation in the UK: an independent report from the Organ Donation Taskforce* (London: Department of Health), available at:

Organs: Whole organ transplants, including kidneys, heart, liver, lungs, pancreas and the small bowel, are carried out in the UK as routine procedures. In the period 2008–9 there were 3,513 whole organ transplants in the UK, donated by 961 living donors and 900 deceased donors.[37] Demand for transplants outstrips the supply of donated organs, with the gap between supply and demand being particularly acute from donors of non-white ethnic origin.[38] In the UK in 2008/09, the number of patients on the active waiting list for an organ transplant increased by 3% per cent to 7,877, and, according to NHS Blood and Transplant, 1,000 people a year will die waiting for an organ.[39]

Paired organ donation: Live donors who wish to provide an organ for a named recipient but who cannot do so because of immunological incompatibility may be 'paired' with another donor/recipient, thus ensuring that two patients receive organs at the same time from compatible donors. 'Pooled' donations work on the same basis with three or more sets of donors/recipients.

Pooled organ donation: see **paired organ donation**

Qualifying relationship: If an adult has not indicated their consent, or refusal, to be an organ donor after death, then the decision may be taken by a person in a 'qualifying relationship' with the deceased person immediately before their death. A hierarchy of relationships is set out in the Human Tissue Act, starting with spouse/partner (including civil partner) and including parent, child, sibling, grandparent, grandchild, niece or nephew, step-parent, half sibling and friend of long standing. Consent is only needed from one person in the hierarchy, and should be obtained from the person ranked highest. If that person refuses, it is not possible to seek consent instead from others ranked lower in the hierarchy.

Reciprocity: Reciprocal relationships, where one party may 'reckon up' what is owed to another, may be seen as a particular, more personalised, form of solidarity (see **Solidarity**). The value of reciprocity may be used to justify some form of benefit-sharing or compensation in return for providing bodily material or participating in a first-in-human trial (see also **Justice**). It also underpins the idea of **paired organ donation** with one donor/recipient 'pair' entering into a reciprocal arrangement with the other. Reciprocity may be invoked negatively, as

---

http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_090303.pdf.

[37] Statistics taken from NHS Blood and Transplant (2009) *Transplant activity in the UK* (London: NHS Blood and Transplant), p7, available at: http://www.organdonation.nhs.uk/ukt/statistics/transplant_activity_report/current_activity_reports/ukt/2008_09/transplant_activity_uk_2008-09.pdf.

[38] Department of Health (2008) *Organs for transplants: a report from the Organ Donation Taskforce* (London: Department of Health), paragraph 1.8.

[39] NHS Blood and Transplant (2009) *Transplant activity in the UK* (London: NHS Blood and Transplant), p4. In addition to the number of patients on the active waiting list, a further 2,385 patients were on the 'temporarily suspended' transplant list. See also http://www.organdonation.nhs.uk/ukt/default.jsp.

in the argument that those who are not prepared to provide bodily material themselves should not be eligible to receive such material themselves, should they come to need it.

Research using human bodily material: A wide range of forms of human bodily material is crucial in medical research. In clinical trials of new medicines, vital information about the effects of the medicine on the individual is obtained from samples of blood and other materials provided by research participants. However, human bodily material also has much wider use in research, from early 'drug discovery' (for example using human tumour samples to discover possible 'targets' for treatment) to later clinical development (for example in order to identify which subgroups of the patient populations respond best to the new medicine).

Saviour siblings: Popular term for children born as a result of 'pre-implantation tissue typing', where embryos created through IVF are tested for tissue compatibility with an existing sibling suffering from a serious inherited disorder. In most cases 'pre-implantation genetic testing' will also be carried out in order to ensure that any resulting child does not suffer from the same disorder. Cord blood taken from the 'saviour sibling' at birth can then be used to treat the older child. The Human Fertilisation and Embryology Authority licenses pre-implantation tissue typing on a case-by-case basis.

Solidarity expresses the idea that 'we're all in this together' with an implication of mutual obligations and mutual support within a community. It could be argued that some of the language used to promote donation in the UK at present is in fact based more on solidarity than on altruism, highlighting the possibility that everyone may at some point have an urgent need to receive donated blood and organs and that hence they have an interest, if not a duty, in donating in their turn.[40] (See also **Reciprocity**.)

Stem cells: Both adult ('multipotent' and 'pluripotent') and embryonic stem cells play an increasingly important role in treatment and research. Adult stem cells derived from bone-marrow are used for the treatment of leukaemia, for example, and considerable research effort is being devoted to the possible use of stem cells for the treatment of diseases such as Parkinson's. Adult cells may be obtained from bone-marrow or from biopsies of solid organs, either when a biopsy is being taken for another purpose, or specifically to obtain stem cells. The harvesting and use of embryonic stem cells is more contentious, as the embryo must then be destroyed.

Tissue: In the Human Tissue Act 2004 the term 'tissue' is used to refer to any, and all, constituent part(s) of the human body formed by cells. In this consultation paper, we use 'tissue' in its more common usage, to refer to human bodily

[40] See, for example, http://www.organdonation.nhs.uk/ukt/adverts/adverts.jsp.

material (consisting of cells) other than solid organs, blood and gametes. See also **Bodily material**.

Tourism (transplant tourism and fertility tourism): This term is used to describe how those on an organ transplant waiting list, or having difficulty obtaining donated gametes in the UK, travel abroad to countries where organs and gametes are more widely available – either because of different regulatory controls, or because of thriving illegal markets where organs and gametes may be bought and sold.[41] There are no official statistics on how many UK residents travel abroad in this way; however the Department of Health has reported that, in 2006, 31 UK residents were followed up in the UK after kidney transplantation abroad. 28 of these kidneys came from live donors.[42]

Transactions. An umbrella concept used in the Terms of Reference to cover all kinds of dealings, here for medical purposes, between persons or agencies with respect to human bodily material.

Transplant infrastructure: In 2006, a UK-wide Organ Donation Taskforce was established with a brief to "identify the obstacles to organ donation and suggest solutions which would deliver the increase in transplants that is so desperately needed.[43] In its subsequent report, published in January 2008, the Taskforce highlighted its belief that a 50% increase in organ donation after death was possible and achievable in the UK within five years, if its recommendations were followed. These included: the establishment of a UK-wide organ donation organisation to facilitate a genuinely nationwide service; the establishment of clinical donation 'champions' and donation committees in every Trust; discussions about donation to be seen as part of all end-of-life care; the routine monitoring of rates of potential donor identification, referral, approach to family and consent; the removal of financial disincentives so that costs did not fall inappropriately on donor hospitals; a UK-wide network of organ retrieval teams; and centralised organisation and employment of donor transplant co-ordinators.

UK Biobank: A research initiative aiming to collect blood, saliva and urine samples from half a million UK volunteers aged 40-69 for ongoing research.[44]

---

41 Heng BC (2006) 'Reproductive tourism': should locally registered fertility doctors be held accountable for channelling patients to foreign medical establishments? *Human Reproduction* **21(3)**: 840–2; Abbud-Filho M, Al-Mousawi M, Alobaidli AA *et al.* (2008) Organ trafficking and transplant tourism and commercialism: the Declaration of Istanbul *Lancet* **372**: 5–6.

42 House of Commons Hansard, 26 February 2008, c1468W, available at http://www.publications.parliament.uk/pa/cm200708/cmhansrd/cm080226/text/80226w0026.htm#0802273001843.

43 Department of Health (2008) *Organs for transplants: a report from the Organ Donation Taskforce* (London: Department of Health), p2.

44 Information taken from the UK Biobank's website '*UK Biobank – what is it?*', available at: http://www.ukbiobank.ac.uk/about/what.php.

Undue influence: There is disagreement as to the extent financial incentives, or incentives with a monetary value, may influence a person 'unduly' in their decision about providing bodily material or participating in a trial. On the one hand there is concern that the offer of payment may encourage people to ignore or overlook risks they would otherwise have rejected.[45] (Such risks may be psychological as well as physical: while a woman 'sharing' her eggs to fund her IVF treatment is not subjecting herself to additional risk as she is already undergoing the procedure, she may be reducing her own chances of conceiving.)

On the other hand, it is argued that it cannot be 'coercive' to offer money without any form of threat or violence: such an offer simply extends the range of choices open to the person.[46] It is also argued that to make an inducement 'undue' it must involve incitement to take "unnecessary, unreasonable, and excessive risks of harm, whether physical harm or the harm of violating important values" which should not apply in properly run clinical trials, or in surgical procedures to remove organs or gametes.[47] Comparisons are often made with accepted practices in other areas of social life such as mining, military service or police work where financial rewards are considered appropriate for individuals undertaking risky or uncomfortable activities.[48] In return, it has been argued that the conduct of medical research is distinct from the other 'ordinary' aspects of social interaction and as such "it would be consistent with this practice to require a higher quality of consent for transactions in human subjects research than we tolerate for transactions in the private sphere".[49] Moreover, the payments offered to participants in first-in-human trials are specifically *not* supposed to be related to risk.

Valid consent: A helpful summary of English common law is provided in the Department of Health's *Reference guide to consent for examination or treatment* (2009), 2nd edition (London: Department of Health).[50] See also the Human Tissue Authority guidance, *Consent: the fundamental principle*, in its code of practice on

---

45 Hale B (2007) Risk, judgement and fairness in research incentives *American Journal of Bioethics* **7(2)**: 82–3.

46 See, for example, Grady C (2005) Payment of clinical research subjects *Journal of Clinical Investigation* **115(7)**: 1681–7; Emanuel EJ (2005) Undue inducement: nonsense on stilts? *American Journal of Bioethics* **5(5)**: 9–13; Frost N (2005) Gather ye shibboleths while ye may *American Journal of Bioethics* **5(5)**: 14–5.

47 Emanuel EJ (2005) Undue inducement: nonsense on stilts? *American Journal of Bioethics* **5(5)**: 9–13 at 10.

48 Radcliffe-Richards J, Daar AS, Guttman RD *et al.* (1998) The case for allowing kidney sales *Lancet* **351**: 1950–2; Monaco AP (2006) Rewards for organ donation: the time has come *Kidney International* **69**: 955–7.

49 Phillips TB (2007) Money, advertising and seduction in human subjects research *American Journal of Bioethics* **7(2)**: 88–90, at 89.

50 Department of Health (2009) *Reference guide to consent for examination or treatment* (London: Department of Health), available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_103643.

consent, which includes links to the consent guidance provided by the Welsh and Northern Ireland health departments.[51]

Ventricular assist device (VAD): mechanical device which may potentially provide an alternative to transplant for those with advanced heart failure in the future, and is presently used to support cardiac function until a transplant becomes available.[52]

Volunteer: the term 'volunteer' is widely used for those choosing to participate in first-in-human clinical trials; as with 'donor' the term is used regardless of whether or not they receive any form of compensation.

[51] Human Tissue Authority (2009) *Code of practice 1: consent,* paragraphs 23–40, available at: http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code1consent.cfm?FaArea1=customwidgets.content_view_1&cit_id=662&cit_parent_cit_id=652.

[52] Krishnamani R, DeNofrio D and Konstam MA (2010) Emerging ventricular assist devices for long-term cardiac support *Nature Reviews Cardiology* **7**: 71–6.