Appendices

Appendix 1: Method of working

Background

The Nuffield Council on Bioethics established the Working Party on *Human bodies: donation for medicine and research* in January 2010. The Working Party met nine times over a period of 17 months. In order to inform its deliberations, it held a public consultation, a deliberative workshop with members of the general public, and a series of 'fact-finding meetings' with external stakeholders and experts. It also commissioned three external evidence reviews from academics working in this area, and sought comments on a draft of the report from thirteen peer reviewers. Further details of each of these aspects of the Working Party's work are given below and in Appendix 2. The Working Party would like to express its gratitude to all those involved, and the invaluable contribution they made to the development of the final report.

Consultation document

The Working Party's consultation document was published in April 2010, and the consultation period extended from April to July 2010. 179 responses were received, of which 116 were submitted by individuals and 63 on behalf of organisations. Those responding to the consultation included members of the public (both those with immediate experience of donation and those with a general interest), patient and user organisations, faith groups, academics and researchers, people involved in regulating donation and research, and professionals involved in transplantation and fertility services. A full list of those responding (excluding those who asked to be anonymous) is set out in Appendix 2, and a summary of the responses is accessible on the Council's website.[714] Copies of individual responses will also be made available on the website, where the Council has permission from respondents to do so.

Fact-finding

As part of its work, the Working Party held a series of 'fact-finding meetings'. These took the form either of lunchtime presentations during Working Party meetings or of half-day events in which invited guests made brief opening statements and then participated in discussion with Working Party members and other guests.

Uses of tissue in treatment and research: 2 March 2010

Dr Ruth Warwick, Consultant Specialist for Tissue Services, NHS Blood and Transplant (since retired) and past President of the British Association of Tissue Banking
Professor Chris Womack, Principal Clinical Histopathologist, AstraZeneca, and Honorary Chair in the School of Cancer and Enabling Sciences, University of Manchester (Working Party member)

Cross-border care: 20 May 2010

Professor Lorraine Culley, Professor of Social Sciences and Health, De Montfort University; currently the principal investigator of Transrep, an exploratory study of UK residents who travel abroad for fertility treatment
Mr Keith Rigg, Consultant Transplant Surgeon, Nottingham University Hospitals NHS Trust (Working Party member)

[714] See: http://www.nuffieldbioethics.org.uk/humanbodies.

Regulation of donation of bodily material and participation in first-in-human trials: 23 June 2010

Sir Gordon Duff, Chairman, Commission on Human Medicines
Dr Pablo Fernandez, Medical Director, PharmaNet (nominated by ABPI)
Ms Danielle Hamm, Policy Manager, Human Fertilisation and Embryology Authority
Ms Jane Juniper, R & D Science Policy Leader UK, AstraZeneca (nominated by ABPI)
Mr Adrian McNeil, Chief Executive of the Human Tissue Authority (since retired)
Mr David Neal, Deputy Director (Policy), National Research Ethics Service
Dr Luc Noel, Co-ordinator, Clinical Procedures, Essential Health Technologies, World Health Organization
Ms Triona Norman, Head of Policy, Organ and Tissue Transplantation, Department of Health
Ms Juliet Tizzard, Head of Policy, Human Fertilisation and Embryology Authority

Opinion Forum on public vs private donation: 2 November 2010

Dr Susan Bewley, Consultant Obstetrician/Maternal Fetal Medicine; Honorary Senior Lecturer, King"s College London
Professor Janet Carsten, Professor of Social and Cultural Anthropology, University of Edinburgh
Dr Antonia Cronin, MRC Centre for Transplantation, King's College London; Chair of British Transplantation Society"s Ethics Committee
Professor Jeanette Edwards, Professor in Social Anthropology, University of Manchester;
Professor Erica Haimes, Founding Executive Director and Professorial Fellow, Policy, Ethics and Life Sciences (PEALS) Research Centre, Newcastle University
Dr Klaus Høyer, Associate Professor, Institute of Public Health, University of Copenhagen

Deliberative event

The Working Party"s consultation document was widely publicised, and it was open to anyone who wished to respond to do so. However, the Working Party was aware that members of the public would only be likely to respond if they had a strong existing interests in the issues raised. Yet the donation of bodily materials has the potential to affect anyone without warning, whether as a potential donor, or as a recipient. The Working Party therefore felt it would be very helpful to find a way of obtaining the views of some members of the public who might otherwise not consider responding to its consultation. A Wellcome Trust People Award enabled the research consultancy Opinion Leader, on behalf of the Working Party, to arrange and facilitate a one day deliberative workshop with recruited members of the public to explore their views on the issues raised by donation and volunteering for research. This took place in Bristol on 26 July 2010 and involved 43 members of the public. The workshop consisted of a mix of plenary sessions, presentations, breakout sessions, and individuals and group exercises. Members of the Working Party took part as speakers and observers, and a detailed report was produced by Opinion Leader.[715] The report drew the following conclusions:

- Participants perceived a moral imperative for society to address any mismatch between supply and demand of bodily material. However, they were concerned that individual donation decisions be in the hands of the donors, with no intervention or coercion from outside parties. Relatives should make donation decisions on behalf of deceased people who had not made their wishes clear. Although consensus could not be reached on how to resolve conflicts between a deceased person who wants to donate and a relative who opposes donation, this was seen as indicating a need for families to discuss their wishes with one another beforehand.
- Participants felt that control of donated materials should be in the hands of healthcare professionals under a transparent and fair system of allocation, with the exception of allowing a donor organ to be given directly from one person to another.

[715] For the full report from Opinion Leader, see: http://www.nuffieldbioethics.org.uk/humanbodies.

- Cash incentives were seen as potentially coercive and unappealing, and were only suitable for recognising the risks involved in taking part in medical trials, or as a contribution to funeral expenses. Benefits in kind, such as a priority for an organ in future, were seen as having potentially negative impacts on medical decision making and so were generally rejected. It was perceived that donations should be recognised through a thank you letter or a token. However, this was not seen as offering a reason to donate, rather an acknowledgment of that person"s decision to donate.

Street Talk stalls organised by nef

The organisation nef (new economics foundation) also received funding in 2010 from the Wellcome Trust in order to test out the effectiveness of using consultation stalls in streets and shopping centres to reach people who would be unlikely to attend public meetings. While this project was carried out independently of the Nuffield Council, nef used the Working Party"s consultation materials as a basis for its 'Street Talk' project. Eight stalls were held in Hereford, London and Manchester, reaching 499 people over 15 days. Participants were invited to comment first on the ethical acceptability, and secondly on the likely effectiveness, of different incentives for donating bodily materials or volunteering to test a new anti-cancer drug. The five incentives suggested were: a letter of thanks, a donation to charity, a token payment, a substantial payment, and payment in kind. The forms of donation considered were joining the Organ Donor Register to donate organs after one"s death, and donating sperm or eggs to help a childless couple. A report produced for the Working Party by nef concluded that:

- 80 per cent of respondents were comfortable with organ donation, and yet less than half of respondents were actually on the ODR.
- Payments of all sizes, for all donation types, were seen as unethical and ineffective by a majority of respondents.
- Payment in kind was seen as more ethical and more effective than payment in money.
- Donations to charity and letters of thanks were viewed as ethical, but not necessarily effective, incentives.[716]

Evidence reviews

In order to inform its deliberations, the Working Party commissioned three evidence reviews from external academics. These covered regulatory approaches in other countries; factors disposing people to donate or not donate; and the effect of incentives on donation practices. The terms of each review are set out below. Because of the vast scale of the literature on donation, it was acknowledged that the reviews could not aim to be comprehensive, and should be regarded rather as snapshots of the available literature in each of these areas.

Review 1: Comparative review of the effects of different regulatory approaches to donated human bodily material and 'healthy volunteer' clinical trials

The brief for Review 1 was as follows:

1. A summary, with reference to the regulatory frameworks in Spain, Belgium, Iran, Israel, India and a North American jurisdiction (e.g. an appropriate US state, with reference where relevant to national regulation/guidance) of:

    a Requirements for consent before human bodily material may be used in medicine or research (including the role of relatives in decision-making)
    b The degree of control a donor of human bodily material may exercise over the donated bodily material (e.g. by directing it to a particular person, or not for a particular use or recipient)

[716] For the full report from nef, see: http://www.nuffieldbioethics.org.uk/humanbodies.

c Any restrictions on commercial dealings in human bodily material and any requirements/prohibitions relating to compensation for the donor
d Any legal provisions as to property ownership of human bodily tissue
e Any legal constraints on payments made to participants in „healthy volunteer" clinical trials.

2. A summary of the available statistics on donation rates in these countries of the various forms of human bodily material for either medical treatment or research, including trend data before and after any regulatory changes, where available. Similarly, summary data on the numbers participating in healthy volunteer trials.

3. A literature review of published studies/reports/articles relevant to the following questions:

   a What is the impact of these regulatory requirements on the availability of human bodily material for medicine and research, or on the numbers participating in healthy volunteer trials?
   b Are the regulatory requirements followed in practice?
   c Are there any confounding factors, such as other legal or policy changes potentially affecting donation rates?
   d What is the quality of the evidence currently available?

The review was carried out by Dr Kathy Liddell, from the Faculty of Law, Cambridge University. In addition to primary legal materials and an extensive English language literature review, Dr Liddell conducted a number of telephone interviews and email exchanges with experts in the relevant countries. Thanks are due to: Anita L Allen (US), Tamar Ashkenazi (Israel), Alireza Bagheri (Iran), Arthur Caplan (US), Maria Casado (Spain), Christine Grady (US), Itziar de Lecuona (Spain), Muireann Quigley (UK), SV Joga Rao (India), and Carlos Romeo Casabona (Spain).

Review 2: review of the evidence as to the factors that dispose individuals to provide human bodily material for treatment or research, or to participate in 'healthy volunteer' trials

The brief for Review 2 was as follows:

We would like to be able to answer the following question:

- What evidence is there as to the factors that dispose individuals to provide (or not to provide) human bodily material for medicine or research, or to participate in a 'healthy volunteer' clinical trial with no expectation of personal health benefit?

'Factors' might include (but not be restricted to) the personal attitudes and views of the person concerned, their religious and/or cultural affiliations, and their personal or family situation (e.g. in regard to health or finance).

Guidance for author

Literature review on the evidence relating to the questions above, including:

- Review of published studies and reports and their findings
- Assessment of the quality of evidence
- Further factors that need to be considered

The review was carried out by Dr Lesley M McGregor and Professor Ronan E O'Carroll, Department of Psychology, University of Stirling, and was divided into two parts, Part 1 covering the donation of bodily material and Part 2 covering healthy volunteer trials. Inclusion and exclusion criteria were subsequently set to the initial brief, in order to make the project more manageable. In Part 1, the search was limited to empirical studies published in journals, carried out in the UK since 2000, and

focussing on potentially modifiable factors relating to motivators and deterrents to donation, as opposed to the personality characteristics of donors and non-donors. Part 2 of the review was restricted to articles written in English and published in peer reviewed journals.

Review 3: review of the impact of offering financial or other incentives to encourage people to donate human bodily material

The brief for Review 3 was as follows:

> We would like to be able to answer the follow questions:
>
> What is the impact of offering incentives (financial or other) to individuals to encourage them to provide human bodily material, of any form, on
>
> - the quantity of material donated?
> - the quality of material donated?
> - the quality of the decision to donate (e.g. does the offer of financial incentives alter perceptions of risk involved)?
>
> Draft guidance for author
>
> - Literature review on the evidence relating to the questions above, including:
> - Review of published studies and reports and their findings, with a particular focus on experimental studies, where available
> - Assessment of the quality of evidence available
> - Further factors that need to be considered
> - Review of research underway in this area

The review was carried out by Dr Burcu Tung and Professor Theresa M Marteau (Working Party member), of King"s College, London. Studies deemed eligible for inclusion were peer-reviewed, experimental or descriptive studies that presented data on the quality and quantity of bodily material provided, and/or the quality of the decision in at least two groups: those providing material when offered a financial incentive, and those providing material with no offer of a financial incentive.

Peer review

An earlier version of the report was reviewed by thirteen individuals with expertise in the areas covered. These were Professor Michael Banner, Professor Peter Braude, Professor Roger Brownsword, Professor Finbarr Cotter, Professor Sarah Franklin, Dr Rosario Isasi, Dr Susan Kerrison, Dr Louise Leong, Professor Eckhardt Nagel, Mr Chris Rudge, Dr Susan Wallace, Professor Heather Widdows and Professor Stephen Wilkinson.

The Working Party deeply appreciates the time and thought that so many individual contributors brought to this investigation.

Appendix 2: Wider consultation for the report

The aim of the public consultation was to obtain views from as wide a range of organisations and individuals interested in donation as possible. The consultation document was published online (available in hard copy on request) and received considerable publicity through the media. Individuals and organisations known to be interested were also directly alerted by email and encouraged to respond. The document was divided into six sections, each containing background information followed by questions. The six sections were:

- the nature of bodily material that may be donated, either during life or after death, to benefit others
- the purposes for which material may be donated
- some of the ethical values at stake
- ways of responding to the demand for bodily material
- the role of consent
- issues of ownership and control over bodily material.

In total, 30 questions were asked, and respondents were encouraged to answer as many, or as few, as they wished. 179 responses were received, 116 from individuals and 63 from organisations. All the responses were circulated to Working Party members, and a summary of responses was considered in detail at a subsequent Working Party meeting.

A summary of the responses received, together with the original consultation paper, is available on the Council's website.[717] Individual responses will also be published in full on the website, where respondents have granted permission for the Council to do so. The responses received played an important role in shaping the Working Party's thinking, and the Working Party is immensely grateful to all those who contributed.

List of respondents to the consultation document

Individuals
Anonymous (15)
Dr Ray Abrahams
Dr Rachel Ariss
Attendees of Ethics Forum at University Hospitals Birmingham, organised by Greg Moorlock
Professor Dr Jayapaul Azariah
Susan Bewley, Consultant Obstetrician
Chris Briscoe
Graham Brushett
Andrew Burrow
Harry Burton
Haris E. Cazlaris, PhD
John Champion, Chair SCKPA
Mrs Cheek
Dr Brian J. Clark
Mr T. J. Coldrick
Alan Craig
Brian Dale
Professor Gabriel Danovitch
Sarah Devaney
Thomas Dillon

[717] See: http://www.nuffieldbioethics.org.uk/humanbodies.

Jayne Doran
Graham Driver
Karen Dyer, Lecturer in Law, University of Buckingham
Dr Howaida Ebead
Dr Miran Epstein
David W. Evans
Dr John Fitton
Michael Fulton
Professor Peter Furness
John Garfield
David Gollancz
C. A. Growney RN
Zeynep Gurtin-Broadbent
Dr Gill Haddow, ESRC Innogen Centre
Phil Harding
Shawn H. E. Harmon
Dr David J. Hill
Rory Holburn
Dewi Hopkins
David H. Howard, Associate Professor, Department of Health Policy and Management, Emory University
Marcia C. Inhorn
Dr Ian Jessiman
Dr Kevin D. Johnston
Mr Mark Kennett
Allan King
Jonathan Lee
Jonathan Lepper
Aaron Long
Grant Mackie
Mrs Kay Mason
Professor Arthur Matas, Department of Surgery, University of Minnesota
Rosanna McArdle
Dr Maryon McDonald
Jeff McILwain MD FRCS
Stewart McKane
Councillor John Meikle MBE
John Miller, Glasgow
Stephen Morris
Richard Mountford
Alex Nolan
Dr Petra Nordqvist, University of Manchester
Anne Oberon
Sylwia Maria Olejarz
M. O'Sullivan
A. C. Palmer
Betty Perry
Miriam Pryke
Dr Muireann Quigley
Sue Rabbitt Roff
Dr Paul M. Rea
Dr J. Reeve
Thomsina Rickard
Professor Charis Thompson
Celia Roberts and Karen Throsby
Marlene Rose, Imperial College
Achim Rosemann
Judith Rowley
R. A. Royall
Professor Robert Rubens

Sally Satel
Miss N. Sethi, AHRC/SCRIPT Centre, School of Law, University of Edinburgh
Lesley A. Sharp, Professor of Anthropology, Barnard College and Senior Research Scientist, Mailman School of Public Health, Columbia University, NY, USA
Alex Smith
Mr G. Smith
Jonathan Smith of Moseleys, solicitors of Lichfield
Pat Spallone
Dr Lindsay Stirton and Jurgen De Wispelaere
David Thewlis and Stuart Taylor
Miss E. J. Toogood
Dr Richard Turner
Joseph L. Verheijde PhD, Mayo Clinic in Arizona
Charles Warlow
Rob Warwick
Lorna Weir, Professor of Sociology and Health, York University, Toronto, Canada
James Westerman
Neil Whitcombe
R. C. Whiting
Heather Widdows and Sean Cordell
Stephen Wilkinson, Professor of Bioethics, Keele University
Amanda Wilson
Simon Woods, Jackie Leach Scully, Pauline McCormack, and Ilke Turkmendag of the Policy Ethics and Life Sciences Research Centre

Organisations
Anonymous (4)
Mario Abbud-Filho, Medical School FAMERP S.J. Rio Preto
Academy of Medical Royal Colleges and Faculties in Scotland
Professor R. Anderson FRCOG, Royal College of Obstetricians and Gynaecologists
The Anscombe Bioethics Centre, Oxford
Asterand
AstraZeneca PLC
Jamie Borg, Guy's and St. Thomas' Foundation Trust
British Fertility Society
British Heart Foundation
British Medical Association
The British Psychological Society
The British Transplantation Society
CARE
Centre for Family Research, University of Cambridge
Christian Medical Fellowship
Church of England - Mission and Public Affairs Council
Declaration of Istanbul Custodian Group
Donor Family Network
European Society for Organ Transplantation Council
Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom
GlaxoSmithKline R&D
HEAL (Health Ethics and Law), University of Southampton
The HeLEX Centre, University of Oxford
Human Tissue Authority (HTA)
Human Tissues Group
Infertility Network (Canada)
International Donor Offspring Alliance
Kidney Research UK
The Lewis Prior Foundation
Liberal Judaism
The Medical Research Council

MRC Centre for Transplantation, King's College London, NIHR Biomedical Research Centre at Guy's and St. Thomas' NHS Foundation Trust and King's College London - Transplant Theme
National Gamete Donation Trust
National Research Ethics Advisors' Panel (NREAP)
Patient Concern
PHG Foundation
Jean-Paul Pirnay, Laboratory for Molecular and Cellular Technology, Military Hospital, Brussels
PROGAR (British Association of Social Workers Project Group on Assisted Reproduction)
Progress Educational Trust
Royal Brompton & Harefield NHS Foundation Trust
Royal College of General Practitioners
Royal College of Pathologists
Royal College of Pathologists Lay Advisory Committee
Royal College of Physicians
Royal College of Physicians of Edinburgh
Patricia Stoat, Convenor, Health and Bioethics Committee, National Board of Catholic Women
UK Donation Ethics Committee
University Hospitals of Coventry and Warwickshire Clinical Ethics Committee
University of Leicester Medical School - group 1
University of Leicester Medical School - group 3
University of Leicester Medical School - group 8
University of Leicester Medical School - group 11
University of Leicester Medical School - group 13
University of Leicester Medical School - group 14
University of Leicester Medical School - group 15
University of Leicester Medical School - group 21
University of Leicester Medical School - group 22
University of Leicester Medical School - group 24
Wellcome Trust

In addition, the Working Party received several submissions drawing our attention to relevant academic papers, and would like to thank Professor Arthur Caplan, Dr Kathryn Ehrich, Dr Scott Halpern, Professor John Harris, Dr Medard Hilhorst, Dr Daniel Sperling, Dr Celia Roberts, Dr Luis A. Tomatis, and Dr Karen Throsby.

Appendix 3: The Working Party

Marilyn Strathern (Chair), recently retired from the Department of Social Anthropology and from the headship of Girton College, both of Cambridge University, has worked on gender relations and legal anthropology in Papua New Guinea and on kinship and the new reproductive technologies in the UK.

Janet Darbyshire is Emeritus Professor of Epidemiology, University College, London, recently retired from the Directorship of the MRC Clinical Trials Unit and Joint Directorship of the NIHR Clinical Research Network. As a clinical epidemiologist, she has worked on the design, conduct and analysis of clinical trials in the UK and internationally, primarily in HIV infection, tuberculosis and cancer, and on the delivery of clinical research in the NHS.

Bobbie Farsides is Professor of Clinical and Biomedical Ethics at Brighton and Sussex Medical School. She was a member of the Organ Donation Taskforce and has gone on to serve on the UK Donation Ethics Committee. She is currently working on an NIHR funded project looking at donation of organs within the South Asian community in the UK. More broadly her research has focused on the experience of scientists and health care professionals working in ethically contested fields such as embryo and stem cell research and pre-implantation genetic diagnosis, including work on establishing an ethical framework for embryo donation for scientific research.

Sian Harding is a Professor of Cardiac Pharmacology at the National Heart and Lung Institute, Imperial College, London. As a basic scientist with a long-standing interest in heart failure, she uses both human myocardial tissue and embryonic stem cells in her work. She is part of the team leading a first-in-human clinical trial for cardiac gene therapy.

Tim Lewens is Reader in Philosophy of the Sciences at the University of Cambridge, where he is also a Fellow of Clare College. His academic work focuses on the philosophy of biology (with a special interest in Darwinism and evolutionary theory), the philosophy of science, and philosophical bioethics.

Gillian Lockwood is Medical Director of Midland Fertility Services and has worked in the field of assisted conception and reproductive medicine for over 20 years. She has a background in philosophy, ethics and economics, and has published widely on the socio-biology of infertility with special reference to gamete donation.

Theresa Marteau is Professor of Health Psychology at King"s College London and Director of the Centre for the Study of Incentives in Health (with the London School of Economics and Queen Mary, University of London). Since January 2011 she is also Director of the Behaviour and Health Research Unit at the Institute of Public Health, University of Cambridge. She studied psychology at the London School of Economics and Political Science, and at the University of Oxford. She is a Fellow of the Academy of Medical Sciences and the Academy of Learned Societies for the Social Sciences.

Naomi Pfeffer is Honorary Research Fellow in the Department of Science & Technology Studies, University College London. She is a medical historian and medical sociologist. Her research interests include infertility and new reproductive technologies, and human tissue collections at the beginning and end of life.

David Price is Professor of Medical Law at De Montfort University School of Law in Leicester where he is Leader of the Healthcare Law Unit. He has been involved in writing and researching aspects of the law and ethics relating to transplantation and the use of human tissue for research for many years, and was a member of the Organ Donation Taskforce investigating the potential impact of an opt out system for organ donation in the UK in 2008.

Keith Rigg is a Consultant Surgeon at Nottingham University Hospitals NHS Trust where he is Director of Transplantation and Vice-chair of the Trust Donation Committee. He has been involved in organ donation and transplantation for over 20 years. He is a non-executive member of the Human

Tissue Authority, Past-President of the British Transplantation Society and has a particular interest in the ethics, public policy and legal issues relating to organ donation and transplantation.

Bob Simpson is a Professor of Anthropology at Durham University. He has written widely on the anthropology of bioethics in relation to new reproductive and genetic technologies, clinical trials and tissue donation. Much of his research has been carried out in South Asia as well as in the UK. He is a former holder of a Wellcome Trust Biomedical Ethics Fellowship.

Chris Womack is a clinical and biobanking histopathologist who worked as a consultant in the NHS for 20 years. He then moved to AstraZeneca Oncology Translational Research in Cheshire where he has responsibility for human sample governance and research programmes to further the understanding of oncology biomarkers in human tissue samples in relation to the development of anti-cancer treatments. He is also pathologist to the Manchester Cancer Research Centre Biobank.

Glossary

Terms in italics are used in this report with a specific definition.

Adipose tissue: Specialised connective tissue that stores energy in the form of fat, also known as fatty tissue.

Adult stem cell: thought to be an undifferentiated cell, found among differentiated cells in a tissue or organ, which can differentiate to yield some or all of the major specialized cell types of that tissue or organ. The primary roles of adult stem cells in a living organism are to maintain and repair the tissue in which they are found. See also **differentiate**.

Allogeneic transplantation: Transplantation of bodily material from one person to another (see also **autologous transplantation**).

Altruism: The concept of 'altruism' is used in many different ways, with one helpful distinction being made between 'motivational' and 'behavioural' definitions of the term. In this report we are concerned with the motivational aspects of altruism, and we define an altruistic action as one that is primarily motivated by concern for the welfare of the recipient of some beneficent behaviour, rather than by concern for the welfare of the person carrying out the action.

Altruistic organ donation: This term is sometimes used to refer to the donation of an organ by a living donor to a person unknown to them, and therefore reflects a very specific use of the term 'altruism'. In this report we use the preferred term 'stranger donation' to describe living organ donation to the common pool (from which organs are allocated on medical criteria), as opposed to donation to a specified individual.

Altruist-focused interventions: Initiatives that seek to change the decision someone is likely to make with respect to donation by removing barriers or disincentives to act. By altering the balance of costs and benefits associated with donation, such initiatives remove countervailing concerns that may prevent altruists from acting on their altruistic motivations. Altruist-focused interventions may also offer some form of token reward or „thank you" (which may take the form of a small financial incentive), on the basis that such tokens of recognition or thanks may act as the final spur for someone already inclined to donate. In order to remain within the definition of 'altruist-focused interventions', however, such tokens must not be sufficient to constitute a primary reason for donating (across the income range). Also see **non-altruist-focused intervention** and **incentive**.

Amniotic membrane: Thin layer of tissue forming the amniotic sac that surrounds the embryo.

Artificial gametes: Eggs or sperm derived from stem cells (currently experimental).

Autologous transplantation: Transplantation of a person's bodily material in their own treatment, either from one part of the body to another, or after storage (see also **allogeneic transplantation**).

Blanket consent: Consent to any further use of donated bodily material, thus allowing it to be used for any legally and ethically approved purpose (see also **generic consent**).

Biobank: See **tissue bank**.

Biomarker: Biological indicators (derived for example from blood, skin, saliva and hair) that can be used to screen for disease and also to monitor disease progression.

Biomolecule: An organic molecule in a living organism.

Biorepository: See **tissue bank**.

Bodily material (in this report): The term „bodily material" is used throughout this report to mean all forms of human biological material that are donated for use in medical treatment and medical research, from individual cells to solid organs. While such material can be deployed in many ways, and may undergo modification, it can only be *obtained* from a person. Note that the definition does not entirely overlap with the definition of 'tissue' in the Human Tissue Act. See also **tissue**.

Bone marrow: The soft tissue filling the cavities of bones. It produces stem cells which produce new blood cells as well as a small population which have the capacity to produce bone, cartilage, fat, and fibrous connective tissue.

Broad consent: A form of generic consent for the future use of donated bodily material, where the donor consents to a wide (but not limitless) range of future uses of their donated material, and an ongoing relationship is maintained between researchers and the donor (see also **generic consent**).

Brain stem death: Death resulting from the irreversible cessation of brain stem function.

Cardiovascular: Relating to the heart and blood vessels.

Cartilage: Hard, thin layer of tissue that covers the end of the bone at a joint.

Cohort: Group of people being studied, usually at different points over time in order to understand how they change.

Commercial dealings (in this report): The giving or receiving of payment that brings profit to the parties involved, typically involving the purchase of an item for which the market sets a price. See also **reward**.

Commodity: An object for which there is demand and which acquires value, typically monetary, when put into circulation with other commodities with which it becomes interchangeable. Such interchange may or may not involve material gain. To turn something into a commodity implies already treating it as an object or 'thing'.

Compensation (in this report): Payment to a person in recognition of non-financial losses they have incurred in donating bodily material, such as time, inconvenience and discomfort. See also **recompense**, **reimbursement** and **reward**.

Congenital: Present from birth and resulting from ante-natal development.

Cord blood: The baby's blood that remains in the placenta and umbilical cord after birth.

Cornea: The clear front part of the eye.

Dataset: Collection of information, organised to be readily retrievable.

DCD (donation after circulatory death): In the UK, donation after circulatory 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 ('controlled' DCD). However, 'uncontrolled' donation after circulatory death, where the donor dies outside hospital of a heart attack, is also possible, despite the inevitable delays before organs may be obtained.

Deceased donation: Donation of bodily material after the death of the donor. Such donation may be authorised in advance by the person concerned, or by others at the time of their death.

Differentiate (of cells): Develop or mature into a more specialised form of cell.

Directed donation: Donation of bodily material to a known recipient.

Donation (in this report): A broad term used to cover voluntary transactions that people might think of as sacrifice, gift or loan, or as simply putting material at the disposal of others, as opposed to some form of 'taking' under coercion or even by seizure. Transactions that involve buying and selling ordinarily share the characteristics of a 'voluntary act', but in the UK it is often thought that the voluntary nature of such transactions is compromised by the element of calculation or financial gain, and many people would contrast such transactions with the making of a gift. However, we follow general UK usage in keeping to the term 'donation' for all kinds of non-coerced disposal.

Egg sharing: Arrangement by which a woman undergoing IVF makes some of her eggs available for another woman's treatment, or for research, in return for free treatment or significantly reduced treatment costs.

Embryo: An embryo is defined in the Human Fertilisation and Embryology Act 1990 (as amended) as including "an egg that is in the process of fertilisation or undergoing any other process capable of resulting in an embryo": section 1(1)(b). An embryo cannot be kept or used for more than 14 days after its creation (excluding any time during which it is frozen): sections 3(3)(a) and 3(4).

Embryonic stem cells (ESCs): Stem cells derived from a fertilised egg after it has started to divide, usually after about five days but never after more than 14 days. ESCs are isolated from the inner cell mass of the embryo that consists of cells not yet committed to developing into any specific cell type (see also **stem cells**).

Fettered consent: See **tiered consent**.

Gametes: Eggs and/or sperm.

Generic consent: Consent for donated bodily material to be used for a range of future (unknown) uses. Generic consent may be **blanket**, **broad**, or **tiered** (see **blanket consent**, **broad consent** and **tiered consent**).

Haematopoietic stem cells (HSCs): Blood stem cells: the precursors of blood cells.

„Hard" opt-out: Legal system in which organs may automatically be taken from people who die in circumstances where their organs are suitable for donation, unless that person has expressed an objection during their lifetime. The family of the deceased is not entitled to veto donation. See also **„soft" opt-out**.

Immunosuppression: Suppression of the immune system, for example to prevent rejection of a transplanted organ.

Incentive (in this report): An offer of money, or other good, over and above the reimbursement of all actual costs incurred in making a donation, with the aim of changing a person's decision with respect to donation. In this report, we distinguish between 'token incentives', where the value or nature of the incentive would be insufficient to provide anyone (regardless of income level) with a primary reason for donating, and incentives that seek to provide that primary motive. See also **altruist-focused intervention** and **non-altruist-focused intervention**.

Induced pluripotent stem cells (iPSCs): Adult cells of various kinds, for example skin cells, that have been transformed into pluripotent stem cells by the introduction of the factors found to be active in embryonic stem cells. iPSCs can then become any cell type in the body, having some similar properties to embryonic stem cells. See also **pluripotent** and **embryonic stem cells**.

Intermediary: Individuals, organisations and institutions that mediate the (often long and complex) chain of transactions between donor and eventual recipient (whether the recipient is another person or an organisation). 'Intermediary' is also used as a specific designation for those personnel who facilitate the donation process in face to face contact with donors and recipients. See **transaction**.

Left ventricular assist device (LVAD): Mechanical pump that can be implanted in a patient in order to help a damaged heart to maintain output.

Ligament: Connective tissue joining bone to bone.

Living donation: Donation of bodily material from a living person.

Loan of body: Providing the whole body on a temporary basis for medical or quasi-medical purposes: these include participating in first-in-human trials where the loaned body is used to test the safety of new medicines, and surrogacy arrangements, where a woman carries a child to term on behalf of others.

Musculoskeletal: Relating to both the muscles and bones.

Nephrectomy: Surgical procedure for the removal of a kidney or part of a kidney.

Non-altruist-focused interventions: Initiatives targeted at potential donors who have no initial strong motivation to help others through the donation of their bodily material, and who therefore need to be provided with different reasons for action, for example in the form of benefits in kind, or of payment going significantly beyond the reimbursement of expenses. See also **incentive** and **altruist-focused intervention**.

Nucleus: Structure within the cell, containing most of the cell"s DNA and controlling the cell"s growth and reproduction.

Oocyte: Egg.

Organ trafficking: Defined in the Declaration of Istanbul as “the recruitment, transport, transfer, harboring or receipt of living or deceased persons or their organs by means of the threat or use of force or other forms of coercion, of abduction, of fraud, of deception, of the abuse of power or of a position of vulnerability, or of the giving to, or the receiving by, a third party of payments or benefits to achieve the transfer of control over the potential donor, for the purpose of exploitation by the removal of organs for transplantation”.

Ovarian cortex: The outer layer of the ovary, containing the ovarian follicles.

Ovarian follicles: Structures in the ovary that develop, under the influence of hormones, from microscopic to 2cm in diameter, at which point they will contain an oocyte capable of fertilisation (at ovulation or at oocyte retrieval during IVF).

Ovarian hyperstimulation syndrome (OHSS): Condition in which a woman"s ovaries over-respond to the hormonal stimulation required during an IVF treatment cycle, producing painful abdominal swelling. The severe form of OHSS is rare but may be life-threatening.

Ovarian pedicle: Contains the ovarian artery and vein that supply blood to the ovary.

Ownership (in this report): In the context of one"s own bodily material, ownership may be understood broadly as entitlement to control over its disposition, once separated from the body, or more narrowly as the possession of a significant bundle of (legally enforceable) property rights. See also **property rights**.

Paired donation: Living 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 donor/recipients.

Parthenogenesis: Process whereby where an unfertilised egg is stimulated to develop into an embryo.

Payment (in this report): A generic term covering all kinds of transactions involving money, and goods with monetary value, whether those transactions are understood as **recompense**, **reward** or **purchase**.

Person (in this report): Used as the primary descriptor of a donor (rather than terms such as individual or self) in order to highlight the fact that people do not act in isolation. The notion of a person implies a social being in relationship(s) with other social beings and as such draws attention to the significance of personal, kinship and economic connections in understanding transactions involving bodily material.

Plasma: The fluid in which all blood cells are carried.

Pluripotent stem cells: Cells that have the potential to develop into many other different kinds of cell.

Pooled donation: See **paired donation**.

Post mortem: Internal examination of the body after death, in order to investigate the cause of death and/or the factors contributing to death.

Pre-implantation genetic diagnosis (PGD): Testing the embryo (created through IVF) for particular genetic conditions, before implantation in the womb. The Human Fertilisation and Embryology Authority must agree that a particular condition is sufficiently serious before clinics are permitted to test for it.

Pre-implantation genetic screening (PGS): Checking the chromosomes of embryos created through IVF for common abnormalities, in order to avoid having abnormal embryos transferred to the womb.

Primordial: In its earliest formation.

Property rights (in this report): Rights that persons have or expect to have with respect to a thing or item, including rights to buy, sell, use, transfer to another, lend to another, exclude others from, and so forth. It is possible to hold some property rights in connection with bodily material (for example those that enable the right-holder to control the use of their bodily material once separated from their body) without necessarily holding others (such as a right to monetary gain from that material).

Prosthesis: An artificial substitute for a body part such as a limb.

Recompense (in this report): A general term for payment made to a person in recognition of losses they have incurred, material or otherwise. In this report, reimbursement of expenses and compensation are both types of recompense (see **reimbursement** and **compensation**).

Reimbursement (in this report): Payment to a person to cover expenses actually incurred in the act of donation, such as travel expenses, meals and lost earnings. Reimbursement returns the person to the same financial position they would have occupied had they not donated, and does not enrich the donor in any way. See also **recompense**, **compensation** and **reward**.

Remuneration (in this report): Material advantage gained by a person as a result of donating bodily material (**reward**), where this is calculated as a wage or equivalent.

Research Ethics Committee (REC): Committee responsible for reviewing research proposals, with the aim of safeguarding the rights, safety, dignity and well-being of people participating in research.

Reward (in this report): Material advantage gained by a person as a result of donating bodily material, that goes beyond 'recompensing' the person for the losses they incurred in donating. 'Reward' is also used in the Human Tissue Act and the Human Tissue (Scotland) Act to mean “any description of financial or other material advantage”.

„Soft" opt-out: Legal system in which organs may automatically be taken from people who die in circumstances where their organs are suitable for donation, unless that person has expressed an objection during their lifetime, or unless the family objects. See also **'hard' opt-out.**

Specific consent: Consent to the use of donated bodily material for a specified project.

Stewardship model: A concept of the role of the state that includes a clear obligation on the part of states to enable people to lead healthy lives.

Stranger donation: The donation of an organ by a living donor to an unknown recipient. Sometimes described as 'altruistic donation': see **altruistic organ donation**.

Supernumerary embryos: Embryos created through IVF that would not be used for a woman"s own treatment.

Superovulation: The medical stimulation of the ovary with hormones to induce the production of multiple egg-containing follicles in a single menstrual cycle.

Tiered consent: A form of generic consent for future use of donated bodily material, where the donor is invited to agree to the future use of their tissue in unknown projects, but given the option of specifying particular categories of research that they wish to exclude (see **generic consent**).

Tissue: In the Human Tissue Act, the term 'tissue' is used to refer to any, and all, constituent part(s) of the human body formed by cells. In this report, we use 'tissue' in its more common usage, to refer to bodily material (consisting of cells) other than solid organs, blood and gametes. See also **bodily material**.

Tissue bank: Repository for a range of bodily materials for treatment or research purposes (also known as biobanks or biorepositories).

Totipotent stem cells: Stem cells with the potential to develop into any kind of cell.

Transaction (in this report): An umbrella concept used to cover all kinds of dealings, here for therapeutic or research purposes, between persons and/or persons and agencies with respect to human bodily material.

Transplant commercialism: Defined in the Declaration of Istanbul as “a policy or practice in which an organ is treated as a commodity, including by being bought or sold or used for material gain”.

Transplant tourism: Colloquial term used to refer to how those waiting for an organ transplant travel abroad to countries where organs are more readily available. It is typically applied to travel for transplantation involving thriving illegal markets where organs are bought and sold. The Declaration of Istanbul distinguishes transplant tourism from other forms of travel for transplantation as follows: “'Travel for transplantation becomes transplant tourism if it involves organ trafficking and/or transplant commercialism or if the resources (organs, professionals, and transplant centres) devoted to providing transplants from outside a country undermine the country's ability to provide transplant services for its own population.”

Valid consent: Consent that meets legal requirements with regard to the capacity of the person making the decision, the adequacy of the information about the nature and purpose of the procedure, and the voluntariness of the decision.

vCJD: Variant Creutzfeldt-Jakob disease, a rare and fatal neurodegenerative disorder, strongly associated with BSE (bovine spongiform encephalopathy) in cattle.

Ventricular assist device (VAD): Mechanical pump that can be implanted in a patient in order to help a damaged heart to maintain output.

Vitrification: An ultra rapid process of freezing gametes or embryos (cryopreservation).

Yearworth (Yearworth and others v North Bristol NHS Trust): a Court of Appeal judgment in which it was held 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.

List of abbreviations

ABPI	Association of the British Pharmaceutical Industry
AMS	Academy of Medical Sciences
ASRM	American Society for Reproductive Medicine
ALSPAC	Avon Longitudinal Study of Parents and Children
BME	black and minority ethnic
BPL	Bio Products Laboratory
CHM	Committee on Human Medicines
CIOMS	Council for International Organizations of Medical Sciences
DBD	donation after brain death (donor)
DCD	donation after circulatory death (donor)
DNA	deoxyribonucleic acid
DonaTE	Donation, Transplantation and Ethnicity
DVLA	Driver and Vehicle Licensing Agency
EC	European Commission
ESC	embryonic stem cell
ESHRE	European Society of Human Reproduction and Embryology
EU	European Union
EUTCD	European Union Tissues and Cells Directive
GATS	(World Trade Organization"s) General Agreement on Trade in Services
GCP	Good Clinical Practice
GDP	gross domestic product
GMP	Good Manufacturing Practice
GP	general practitioner
GWAS	genome-wide association studies
HFEA	Human Fertilisation and Embryology Authority
HIV	human immunodeficiency virus
HRA	Health Research Agency

HSC	haematopoietic stem cell
HTA	Human Tissue Authority
HUGO	Human Genome Organisation
ICSI	intracytoplasmic sperm injection
INUK	Infertility Network UK
iPSC	induced pluripotent stem cell
IVF	*in vitro* fertilisation
LVAD	left ventricular assist device
ME	myalgic encephalitis
MHRA	Medicines and Healthcare products Regulation Agency
MRC	Medical Research Council
NBS	National Blood Service
nef	new economics foundation
NGDT	National Gamete Donation Trust
NGO	non-governmental organisation
NHS	National Health Service
NHSBT	NHS Blood and Transplant
NICE	National Institute for Health and Clinical Excellence
NOTA	National Organ Transplantation Act (US)
NRES	National Research Ethics Service
ODR	Organ Donor Register
ODT	Organ Donation Taskforce
OHSS	ovarian hyperstimulation syndrome
PCT	primary care trust
PET	Progress Educational Trust
PGD	pre-implantation genetic diagnosis
PGS	pre-implantation genetic screening
PPP	public–private partnership

R&D	research and development
REC	research ethics committee
SaBTO	Advisory Committee on the Safety of Blood, Tissue and Organs
SC4SM	Stem Cells for Safer Medicine
SN-OD	specialist nurse for organ donation
TOPS	The Overvolunteering Prevention System
Transrep	Trans-national Reproduction Study
UK	United Kingdom
UKDEC	UK Donation Ethics Committee
UKSCB	UK Stem Cell Bank
UN	United Nations
US	United States
VAD	ventricular assist device
vCJD	variant Creutzfeldt–Jakob disease
WHO	World Health Organization
WMA	World Medical Association