Chapter 2

Regulatory landscape: overview
Chapter 2 - Regulatory landscape: overview

### Chapter overview

- Regulations within the UK governing the donation, storage and use of bodily material generally include requirements for consent and safety, provision as to future control of material once separate from the body, and restrictions on commercial dealings in bodily material. Nevertheless, the detailed aspects of regulation vary significantly both in terms of the form of bodily material, and the purposes for which it has been donated.

- 'Regulation' may prohibit, require, or permit particular actions. Where regulation is permissive, its actual impact is likely to depend on the extent to which the permitted activity is supported, encouraged or, on the contrary, discouraged – and hence will be strongly influenced by the approach taken by relevant organisations. In the UK these at present include the Human Tissue Authority (HTA), the Human Fertilisation and Embryology Authority (HFEA), NHS Blood and Transplant (NHSBT), and individual NHS bodies. Both the HTA and HFEA are due to be abolished by 2015, with their functions absorbed into other statutory bodies, and the English NHS is currently undergoing a process of organisational change. This current state of fluidity in organisational and regulatory infrastructure has been important in the Council's consideration of the practical implications of possible policy recommendations.

- Although the primary focus of this report concerns donation practice within the UK, regulation of the donation and use of human bodily material cannot be confined within national borders. European Union (EU) legislation must be made effective within the UK, and international principles and declarations that seek to set minimum standards world-wide influence regulatory and public attitudes within individual countries. Both people and bodily materials cross national boundaries, and hence regulatory frameworks within other jurisdictions may have a direct impact on UK residents who choose to travel to other jurisdictions for treatment they are unable to access at home. Bodily materials used within the UK may be imported from other jurisdictions where they were donated under different regulatory frameworks; and in some circumstances material donated in the UK may similarly be used abroad.

- Bodily material thus circulates within a global market-place: while almost all countries prohibit financial gain arising directly out of the donation of bodily material (gametes being a common exception), money exchanges hands in connection with the many medical and technical services required to handle and process that material, whether for treatment or research purposes. In order to achieve some clarity in this area, we propose the following terminology in respect of payments made in connection with bodily material:

  - **Payment**: a generic term covering all kinds of transactions involving money, and goods with monetary value, whether those transactions are understood as recompense, reward or purchases;
  - **Recompense**: payment to a person in recognition of losses they have incurred, material or otherwise. This may take the form of the reimbursement of direct financial expenses incurred in donating bodily material (such as train fares and lost earnings); or compensation for non-financial losses (such as inconvenience, discomfort and time);
  - **Reward**: 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. If reward is calculated as a wage or equivalent it becomes remuneration;
  - **Purchase**: payment in direct exchange for a ‘thing’ (e.g. a certain amount for a kidney, or per egg).

### Introduction

2.1 Since the publication of the Council’s report *Human tissue: ethical and legal issues* in 1995, the regulatory frameworks governing the donation, storage and use of human bodily material have changed and multiplied, leading to a very different regulatory environment from 15 years ago. This chapter first provides an overview of key aspects of the regulatory frameworks, highlighting similarities and differences in the way various forms of bodily material are treated in areas such as consent, control, commercial transactions, and safety; and with respect to their future proposed use. It then goes on to consider some of the contexts of scientific development, medical scandal and social change that have influenced the development of the frameworks governing organs and tissue, blood, reproductive materials and first-in-human trials within England/Wales/Northern Ireland, Scotland, and the EU; and to discuss the areas of concern raised with us by the regulators. We note here that ‘regulation’ may be understood and invoked in a variety of different ways: regulation may prohibit particular actions; it may require particular actions; or it may permit particular actions. Where regulation is permissive, then its actual
impact is likely to depend on the facilitative regimes in place: that is, on the extent to which the permitted activity is supported, encouraged or, on the contrary, discouraged. To the extent that regulation is permissive, therefore, the approach taken by influential organisations will be central in determining its effect.

2.2 As demonstrated by the growing phenomenon of individuals travelling abroad for treatment that may not be available or affordable in their own country (colloquially known as ‘medical tourism’\(^{85}\)), regulation of the donation and use of human bodily material cannot be wholly confined within national borders. Moreover, it is not just patients or would-be patients who cross national boundaries. Health professionals, scientists, and investigators carrying out clinical trials all travel widely too, pharmaceutical companies have global reach, and bodily material itself is becoming ever more transportable as storage techniques have developed.\(^{84}\) Such international movement may be the unintended consequence of differing regulatory approaches (see, for example, the increasing trend to ‘out-source’ clinical trials to countries where regulation is perceived to be lighter or populations are less likely to have received previous medical interventions and costs are less\(^{85}\)) or may, by contrast, result from an express political aim, as for example under the World Trade Organization’s General Agreement on Trade in Services (GATS 1995), which seeks to encourage global trade through the removal of protectionist barriers.\(^{86}\) We therefore highlight international principles and declarations that seek to set minimum standards worldwide, and sketch out the regulatory frameworks in a number of other countries to indicate the range of regulatory approaches currently in existence.

2.3 Key legal and policy instruments that govern the donation, storage and use of human bodily material in the UK include those listed below.

- The Human Tissue Act 2004 governs the removal, storage and use of organs and tissue, other than reproductive tissue, within England, Wales and Northern Ireland.\(^{87}\) Its regulatory functions are currently performed by the HTA (but see paragraph 2.5), and detailed guidance on its requirements are set out in statutory Codes of Practice.
- The Human Tissue (Scotland) Act 2006 governs three distinct uses of human bodily material in Scotland: donation for transplantation, research, training and audit; removal, retention and use of material after a post-mortem examination; and donation of the whole body to medical science. The Act does not establish a regulatory authority; however by agreement with Scottish Ministers, the HTA oversees arrangements for living organ donation in Scotland as well as in the rest of the UK.\(^{88}\)
- The Human Fertilisation and Embryology Act 1990, as amended and supplemented by the Human Fertilisation and Embryology Act 2008, sets out the required standards for the use of human gametes and embryos in fertility treatment and research within the whole of the UK.

---

\(^{83}\) ‘Transplant tourism’ and ‘cross-border reproductive care’ are particular examples of medical tourism: they are the source of specific ethical concerns that may not arise in other forms of medical tourism in that they may involve activities that may be illegal in the patient’s home country, or indeed also in the country where the treatment is being provided.


\(^{86}\) For a discussion of the importance of GATS to health policy, see World Health Organization (2004) GATS and health related services: managing liberalization of trade in services from a health policy perspective, available at: [http://www.searo.who.int/LinkFiles/Global_Trade_and_Health_GTH_No6.pdf](http://www.searo.who.int/LinkFiles/Global_Trade_and_Health_GTH_No6.pdf). Under the GATS, governments may choose (or not) to trade health services to achieve their national health objectives, and some have encouraged health care exports (classified as ’mode 2’ or ’consumption abroad’) through treating foreign patients entering their territory, on the grounds that they promote economic development, boost reserves of foreign currencies, and create a more favourable balance-of-trade position. The EU is also subject to the GATS and member states are obliged to allow free movement of services and goods within the union.

\(^{87}\) The Act’s powers with respect to the removal of bodily material are limited to material removed after death; however its powers with respect to the storage and use of bodily material cover material removed both during life and after death.

Its provisions are currently supervised by the HFEA (but see paragraph 2.5 below), and again detailed guidance is found in a statutory Code of Practice.

- The Medicines for Human Use (Clinical Trials) Regulations 2004 provide the regulatory framework for all clinical trials of medicinal products within the UK, including healthy volunteer ‘first-in-human’ trials, and implement the requirements of the EU Clinical Trials Directive.
- The Blood Safety and Quality Regulations 2005 set out the regulatory requirements for blood and blood components throughout the UK. These regulations implement European Directives on blood quality and safety, and make the MHRA responsible for maintaining standards of quality and safety in the collection, testing, processing, storage and distribution of human blood and blood components.
- The NHS Research Governance Framework sets out principles of good research governance that apply to all research carried out within the NHS in England. Similar guidance is available in Scotland, Wales, and Northern Ireland.
- The European Union Tissues and Cells Directives (EUTCD) set out a harmonised approach to the regulation of tissue and cells (including reproductive material) across Europe, setting minimum standards to be met when carrying out any activity involving tissue for therapeutic purposes. The Directives have been implemented in the UK primarily through the Human Tissue Act and the Human Fertilisation and Embryology Act, and the HTA and the HFEA are currently designated as the ‘competent bodies’ responsible for ensuring that the Directives’ requirements are met in the UK.
- The European Union Organ Directive 2010/45/EU concerning "standards of quality and safety of human organs intended for transplantation" came into force in July 2010, and is due to be implemented by all member states by August 2012. The HTA has been designated as the ‘competent body’ responsible for ensuring the requirements of the Directive are met in the UK.

2.4 In addition to domestic and European law, there are many relevant international conventions and statements that may influence UK policy on the donation and use of human bodily material and on participation as a healthy volunteer in first-in-human clinical trials, without being legally binding.

- The Council of Europe’s Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine, known as the Oviedo Convention, requires signatories to "protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine." The
Convention was extended in 2002 by an additional protocol on "transplantation of organs and tissues of human origin" (excluding reproductive material and blood);¹⁰¹ and in 2005 by an additional protocol "concerning biomedical research".¹⁰² The UK is not at present a signatory to the Convention.¹⁰³

- Further guidance regarding research use of bodily material from the Council of Europe was issued in 2006 in the shape of a Recommendation of the Committee of Ministers to member states on research on biological materials of human origin. The Recommendation applies "to the full range of research activities in the health field involving the removal of biological materials of human origin to be stored for research use," excluding embryonic or fetal tissue.¹⁰⁴

- The World Health Organization (WHO) first issued Guiding Principles on human organ transplantation in 1991. A revised and expanded version of these Principles, covering both organs and tissue (excluding reproductive material), was endorsed by the 63rd World Health Assembly on 21 May 2010.¹⁰⁵

- The Declaration of Istanbul on Organ Trafficking and Transplant Tourism was formulated in 2008 by a summit meeting convened by The Transplantation Society and the International Society of Nephrology, in response to concerns about the sale and trafficking of organs. The Declaration states that "organ trafficking and transplant tourism violate the principles of equity, justice and respect for human dignity and should be prohibited", and called for action to prevent the purchase and sale of human organs, along with ancillary activities such as advertising, medical screening and transport.¹⁰⁶

- The Declaration of Helsinki has been developed by the World Medical Association as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.¹⁰⁷

- International Ethical guidelines for biomedical research involving human subjects were first published in 1993 by the Council for International Organizations of Medical Sciences (CIOMS), in association with WHO, and revised in 2002.¹⁰⁸

2.5 Regulation at both UK and EU level implies the existence of regulatory bodies to implement the law. The HFEA and the HTA were established by the Human Fertilisation and Embryology Act 1990 and the Human Tissue Act 2004 respectively, to undertake the regulatory roles set out in the legislation. However, this aspect of the UK regulatory landscape is currently in a state of flux, since the Department of Health announcement in July 2010 that both bodies would be

---


¹⁰³ House of Commons Hansard (4 December 2002) c907W, available at: http://www.parliament.the-stationery-office.co.uk/pa/cm200203/cmhansrd/v021204/text/21204w29.htm. However, it is possible that aspects of the Oviedo Convention could indirectly affect UK law, through influencing interpretations of the European Convention on Human Rights (which in turn is directly applicable within the UK through the Human Rights Act 1998).


abolished before the end of the current Parliament (i.e. 2015). The Department of Health has stated that the regulatory framework itself will not change, but rather that the functions of the two ‘arm’s length’ bodies "will be transferred to other organisations to achieve greater synergies where appropriate". The Government’s aim is in future to have one regulatory body concerned with quality issues, one with economic matters, one with medicines and devices, and one with research. Precisely how these regulatory bodies will absorb the current functions of the HFEA and HTA is currently unclear. Further proposed changes to the NHS in England include the abolition of primary care trusts (PCTs; currently responsible for commissioning health services for their local populations) and the transfer of their functions to consortia of general practitioners (GPs).

Consent

2.6 The need for consent is at the heart of all current systems of regulatory control governing the donation and use of human bodily material. However, the nature of the consent required – including who may provide it, how ‘informed’ it must be, what procedural safeguards surround it – varies, depending on the form of the material, and also on the jurisdiction concerned.

Valid consent for medical procedures and research participation

2.7 The ‘valid’ consent of participants in both medical research and medical procedures is a standard ethical and legal requirement around the world. In the UK, common law governs both consent to treatment and consent to research participation (with additional provisions and safeguards added through legislation as indicated below). The medical procedures involved in donating bodily material as a living donor, from providing a blood sample for a research project to undergoing an operation to donate eggs or a kidney, are governed by the same common law framework as consent to medical treatment for one’s own benefit. Under the common law, consent for the procedures involved in donating bodily material will only be valid if the person giving consent:

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

Under common law, there is no requirement that consent should be in writing. The existence of a signed consent form is simply evidence (which may be rebutted) that consent has been sought and given.

2.8 Where an adult (that is, an individual aged 18 years or over) has the capacity to decide for themselves whether or not to provide some form of bodily material while living, only that adult can provide consent. In England, Wales and Northern Ireland, a child of sufficient maturity and understanding, regardless of age, can provide valid consent to the donation of bodily material such as bone marrow, although court approval should be sought for the donation of an organ or

---

110 Ibid, paragraph 3.3.
111 Ibid, paragraph 3.10.
113 We follow here legal norms in the UK in referring to ‘valid’ rather than ‘informed’ consent when referring to legal requirements. What is required for legally valid consent may differ in different circumstances, a point to which we return in Chapter 5. However, the term ‘informed consent’ is routinely used in guidance on research involvement: see, for example, World Medical Association (2008) WMA Declaration of Helsinki: ethical principles for medical research involving human subjects, available at: http://www.wma.net/en/30publications/10policies/b3/index.html.pdf?print-media-type&footer-right=page/0/toPage.0.
part organ.\textsuperscript{115} If the child is not legally 'competent' in this way, or prefers someone else to make
the decision, a person with parental responsibility may do so, on the basis of the child’s best
interests.\textsuperscript{116} Children who are not competent to provide a valid consent on their own (for
example to provide a blood sample for a longitudinal study) may still be invited to 'assent',
alongside their parent's consent.

2.9 An adult who lacks capacity to make a decision to provide bodily material for use in another’s
medical treatment may only be considered as a donor if it is judged to be in that adult's own
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'.\textsuperscript{117} Adults lacking capacity may only participate
in clinical trials if the procedures either produce a benefit to the subject or produce no risk at
all.\textsuperscript{118}

2.10 In Scotland, young people of 16 years and above are presumed to have capacity to consent for
themselves.\textsuperscript{119} Children under 16 years 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.\textsuperscript{120} Under the Human Tissue
(Scotland) Act 2006, a child aged 12 years or above may also give a written authorisation to
donate organs after their death.

2.11 Valid consent requirements apply not only to the process of donating bodily material, but also to
the retention and use of any associated personal details and health-related information from the
donor. In the case of transplantation, the ability to trace the donated material back to the donor
is important (see paragraph 2.54), while in the case of research, medical information associated
with donated samples will add considerably to the research value of the material (see paragraph
1.13). When being asked for valid consent for the retention of information, the donor should be
clear as to the nature of the information being retained: for example, whether an ongoing link is
envisioned to the donor’s health records; or whether a more limited dataset of information will be
extracted from the person’s records or provided at the time of donation in questionnaire form,
and then linked permanently to the sample. It is also important that the person understands
what procedures are in place to protect their privacy: for example whether material is being fully
anonymised (so that no link can ever be made back to the donor’s personal details such as
name and address); or whether a code will be used to enable linkage to be made between the
sample, the available data, and the donor’s personal details. In the latter case, researchers will
not have access to the 'key' to the code, and hence will never see the donor’s personal details.
Even under such systems, complete anonymity cannot be promised, as in some cases the
material may be sufficiently exceptional (for example a very rare tumour) for a particular
researcher/clinician to identify its source. However, in all cases, researchers working with

\textsuperscript{115} Scrutiny by a panel of three HTA independent assessors is also required if a proposed living organ donor is under 18 years: Human Tissue Authority (nd) Guidance for transplant teams and independent assessors: living donor transplantation, available at: http://www.hta.gov.uk/dbi_documents/IA_Guidance_FINAL_201101045322.pdf, paragraph 44.

\textsuperscript{116} Human Tissue Authority (2008) Human Tissue Act code of practice 1, available at:
http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code1consent.cfm, paragraph 142.

\textsuperscript{117} Mental Capacity Act 2005, section 31.

\textsuperscript{118} The Medicines for Human Use (Clinical Trials) Regulations 2004, as amended, Schedule 1, Part 5.

\textsuperscript{119} Age of Legal Capacity (Scotland) Act 1991, section 1.

donated tissue and associated data will be bound both by a professional duty of confidentiality and the requirements of the Data Protection Act.\(^{121}\)

**Additional ethical oversight of consent procedures in medical research**

2.12 While the requirements for valid consent are the same for research participation as they are for medical treatment, additional protections are in place for research participants through the requirements for review by Research Ethics Committees (RECs).\(^{122}\) Such scrutiny is required for any research categorised as a clinical trial by the Clinical Trials Regulations,\(^{123}\) and for any research carried out within the NHS (that is, involving NHS staff, premises, patients or data).\(^{124}\) REC scrutiny includes consideration of the adequacy of the information available to potential participants when making their decision whether or not to participate, and scrutiny of any payment offered (see paragraph 2.34). The Clinical Trials Regulations further specify that all participants in clinical trials should have an interview with a member of the investigating team in which they should be "given the opportunity to understand the objectives, risks and inconveniences of the trial".\(^{125}\) Consent by research participants will usually be given in writing.

**Scope of consent for material donated for research**

2.13 When consent is sought for the storage and use of a person's bodily material for research purposes, the scope of that consent may vary considerably. The person providing the material may be asked for:

- *specific* consent: for a particular research project or projects which can be clearly described at the time the donation is made (future use for other purposes without new consent not usually permitted); and/or
- *generic* consent: permitting use in future (approved) research projects. By definition, details of such potential projects cannot be provided at the time the consent is sought.

Generic consent may be understood as 'blanket' consent, where no limits at all are placed on the future use of the material. However, 'fettered' or 'tiered' consent may also be seen as categories of generic consent: these terms refer to consent where the participant 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. Where such options are offered to potential donors, it is clearly important that information systems are in place to ensure that the chosen exclusions are properly recorded and maintained. The concept of 'broad' consent, envisaging a wide (but not limitless) range of future uses, together with an ongoing relationship between the researchers and the donors, is a further category of generic consent that is increasingly being used. Such a relationship might involve regular information for donors about the progress and outcomes of research projects, and provide the opportunity for donors


\(^{122}\) These have long been in place as a matter of policy, but now have a statutory basis in the UK as a result of the Clinical Trials Directive 2004.

\(^{123}\) Defined as: "any investigation in human subjects, other than a non-interventional trial, intended (a) to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products, (b) to identify any adverse reactions to one or more such products, or (c) to study absorption, distribution, metabolism and excretion of one or more such products, with the object of ascertaining the safety or efficacy of those products" – Regulation 2 of the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, as amended.


\(^{125}\) Medicines for Human Use (Clinical Trials) Regulations, SI 2004/1031, as amended, Schedule 1, Part 3.
specifically to opt in or out of their donated material being used in particular research projects in the future.\textsuperscript{126}

2.14 The Code of Practice issued under the Human Tissue Act recommends the use of generic consent, in order to facilitate the use of human tissue in research: by definition, such consent permits the use of donated material for future research projects without the need to trace donors, perhaps many years later, to seek further consent.\textsuperscript{127} A ‘vision document’ for human tissue resources, published in 2011 by the major UK funders of research using human tissue, similarly advocates generic consent; indeed it goes further by suggesting that funders should require researchers routinely to request generic consent (in addition, where appropriate, to specific consent for a particular project) as a condition of their funding.\textsuperscript{128} Some major projects holding population data and samples, such as UK Biobank (see paragraph 1.16), have already adopted the approach of broad consent, with the aim of maintaining a more active relationship with their donors. The initial information leaflet provided to potential UK Biobank participants, for example, makes clear that taking part in UK Biobank may involve being re-contacted (although any request to provide further information or samples would clearly be optional); and updates on ongoing research are regularly provided to its ‘supporters’ (the term used by UK Biobank for those who have provided samples and medical information).\textsuperscript{129}

‘Appropriate consent’ for the removal of material after death

2.15 The Human Tissue Act 2004 requires that “appropriate consent” must be given before any bodily material may be taken from the deceased for “scheduled purposes” such as transplantation or research.\textsuperscript{130} Definitions of appropriate consent in the Act relate primarily to the identity of the person who is able to provide the consent: that is, the deceased person if he or she has made a clear decision before their death; a representative nominated for this purpose by the deceased person; or a person in a "qualifying relationship" with the deceased person. The Act sets out a hierarchy of qualifying relationships: this starts with the spouse/partner (including civil partner) and moves through the categories of 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 relevant category, and should be obtained from a person in the highest ranked category available. If this person refuses, their answer is taken as final: it is not possible to seek consent instead from others.\textsuperscript{131} However, while the Act itself does not specify the nature of 'appropriate consent', the Code of Practice on consent issued by the HTA makes clear that consent under the Act must also meet the requirements of ‘valid consent’ described above (see paragraph 2.7). In Scotland, a similar approach is taken, although the legislation uses different terminology: the removal or use of any part of a person’s body after death is only permitted in circumstances where either the person has ‘authorised’ this before their death, or the person’s ‘nearest relative’ (defined in a similar way to the ‘qualifying relative’ elsewhere in the UK) provides the authorisation in their place.\textsuperscript{132} Guidance issued by the Scottish Government makes it clear that the two terms should be treated as equivalent, and that

\textsuperscript{129} For more detail, see the UK Biobank website: UK Biobank (2010) UK Biobank: improving the health of future generations, available at: http://www.ukbiobank.ac.uk/.
\textsuperscript{130} ‘Scheduled purposes’ are set out Schedule 1 of the Human Tissue Act 2004, and also include anatomical examination; determining the cause of death; obtaining scientific or medical information that may be relevant to another person (including a future person); and public display.
\textsuperscript{131} Human Tissue Act 2004, sections 3 and 27.
\textsuperscript{132} Human Tissue (Scotland) Act 2006, sections 6, 7 and 50.
this equivalence is "an essential part of the continuation of the arrangements for sharing organs and tissue across the UK in order to obtain the best outcomes for recipients".\textsuperscript{133}

2.16 Despite the emphasis on valid consent (including sufficient information) in the HTA Code of Practice, there is in practice little, if any, control over how much information is available to individuals when they decide to sign up to the ODR. The Organ Donation Taskforce raised this issue as a matter of concern in its 2008 report, noting that "when seeking to increase the number of registered donors, agencies must ensure that sufficient and appropriate information is provided to be sure that consent is valid and robust".\textsuperscript{134} More recently, a report considering the robustness of the data held by the ODR suggested that the necessary level of information could appropriately be conveyed by sending out ‘Q&A’ information from the NHSBT website to new registrants as part of their ‘thank you pack’, along with guidance on how to change registration wishes, and that it would not be necessary to introduce any kind of additional confirmation stage.\textsuperscript{135}

\textbf{Consent for the storage and use of bodily material}

2.17 Under the Human Tissue Act 2004, appropriate consent is also required for the storage and use of (non-reproductive) material taken from both living and deceased donors. There are some limited exceptions, however, in connection with material taken from living patients in connection with their own treatment, and where the material is no longer needed for the patient’s own care. Such material may be stored and used for a number of further purposes without consent, including for clinical audit; education or training related to human health; public health monitoring; and quality assurance.\textsuperscript{136}

2.18 This is on the basis that these activities are a necessary part of providing a safe and high-quality health service, and that it would therefore not be appropriate to give patients the option of ‘opting-out’ of such essential activity.\textsuperscript{137} These exceptions to the general rule that consent is always required for storage and use do not apply to material taken from the deceased.

\textbf{Exceptions to consent procedures for medical research}

2.19 Under the Human Tissue Act, it may also be permissible to store and use (non-reproductive) material from living donors for research without consent if both the following criteria are met:

- the researcher is not in a position to identify the person from whom the material came; and
- a REC has approved the research proposal, in the knowledge that explicit consent to this use of the material has not been obtained. (Consent would, of course, have had to have been obtained for the initial taking of the tissue.)\textsuperscript{138}

This exception applies both where individuals have provided the initial material for a specific research project, and where the material is ‘residual’ blood or tissue left over from diagnostic procedures. These exemptions do not, however, apply to material taken after death, where consent must be in place for any future storage or use.


2.20 Detailed recommendations by the Council of Europe regarding the use of bodily material in research similarly place emphasis on the importance of seeking appropriate consent for the future research use of 'residual' material, but permit research on identifiable bodily material without such consent (subject to ethical review) if all four of the following conditions are met:

- it is not possible with reasonable efforts to contact the person to seek consent; and
- there is no evidence that the person had expressly opposed such research use; and
- the research addresses an important scientific interest; and
- the research cannot be reasonably achieved using material where consent can be obtained.

The Council of Europe Recommendation also permits the use of 'unlinked anonymised' bodily material (that is, material that can no longer be traced back to its original donor source and hence where confidentiality concerns should no longer apply) without consent, provided that the research does not violate any restrictions placed by the person before the removal of anonymity.139

'Effective consent' for the storage and use of gametes

2.21 The Human Fertilisation and Embryology Act requires written consent for the storage and future use of donated sperm, eggs or embryos.140 Clinics licensed to provide such facilities are required to ensure that such consent is 'effective': that is, it has not been withdrawn. The HFEA Code of Practice sets out detailed requirements as to the information that must be provided before consent is sought, in order to ensure that donors have:

- enough information to enable them to understand the nature, purpose and implications of their treatment or donation;
- a suitable opportunity to receive proper counselling about the implications of the steps that they are considering taking; and
- information about the procedure for varying or withdrawing any consent given, and about the implications of doing so.141

Along with 'effective consent' for the use of gametes, clinics must also ensure that they take proper account of the welfare of the future child, before providing treatment.

Approach to consent at the European and international level

2.22 The EU Tissues and Cells Directive and the EU Organ Directive (see paragraph 2.3) also make reference to need for consent before any kind of material is taken from a person, living or deceased. However, as described in more detail below (see paragraph 2.26), approaches to consent for the removal of organs and other tissue after death vary considerably across member states, with some such as Spain, Belgium and Austria providing for the removal of organs from anyone after their death as long as they had not, in their lifetime, registered their objection (the so-called 'opt-out' approach to organ donation). The Organ Directive therefore simply requires compliance with the requirements "relating to consent, authorisation or absence of any objection" in force in the member state in question, while emphasising in its introductory recitals the importance of a living donor being in a position to take "an independent decision on the basis of all the relevant information."142 The Tissues and Cells Directive also requires that

---

consent procedures be determined by member states, although it specifies necessary informational requirements for living and deceased donors respectively. The WHO's Guiding Principles (see paragraph 2.4) permit cells, tissues and organs to be removed from the body of a deceased person if any consent required by law is obtained, and if there is no reason to believe that the deceased person objected.

2.23 The Oviedo Convention and additional protocol (see paragraph 2.4) similarly recognise that approaches to consent vary significantly across Europe. The protocol's requirements as regard consent for the use of organs or tissue after death echo those of the EU Directives, specifying that the "consent or authorisation required by law" must have been obtained, and that material may not be removed if the deceased person had objected. However, it is more specific with respect to living donors, requiring the "free, informed and specific consent" of the donor, who may freely withdraw consent at any time. The Convention itself also specifies that body parts may only be used for a different purpose from that from which they were removed if this is done "in conformity with appropriate information and consent procedures".

Additional protections for living donors

2.24 Domestic legislation within the UK, EU Directives and Council of Europe instruments all recognise, in various forms, the need for particular protection of living donors, especially as regards living organ donation. In the UK, the HTA regulates all living organ donations, with the aim of ensuring that the consent provided by the living donor is fully informed and that there is no evidence of coercion, duress or reward (for definition of 'reward' in the Human Tissue Act, see paragraph 2.34). Donors are only accepted after detailed medical and psychosocial assessment, along with assessment of the organs themselves. Where a person is offering to donate an organ to a stranger, rather than to a relative or friend, approval must first be sought from a panel of at least three members of the HTA; the same process applies to 'pooled' and 'paired' donations (see paragraph 3.60). The EU Organ Directive requires that "the highest possible protection of living donors should be ensured".

2.25 The Oviedo Convention and its additional protocol on transplantation similarly recognise the risk both of duress and of physical harm to the donor: the protocol specifies, for example, that organ removal from a living donor may only take place where the donor has a close personal relationship with the recipient, or under conditions defined by law and with the approval of an independent body. It also explicitly bans organ or tissue removal that would pose a serious risk to the life or health of the donor. The Convention, however, goes further than domestic legislation within the UK, specifying that the removal of organs or tissue from a living person for transplantation purposes should only be carried out where there is no suitable organ or tissue available from a deceased person, and where no other alternative therapeutic method of comparable effectiveness is available. The WHO's Guiding Principles demonstrate similar concerns in urging that donation from deceased persons should be "developed to its maximum therapeutic potential", and in stating that in general living donors should be genetically, legally or emotionally related to their recipients.

148 Ibid, Article 11.
Comparisons with other jurisdictions

2.26 The Working Party commissioned a review of the legal provisions affecting donation in a number of other jurisdictions, in order to obtain a snapshot of a range of regulatory approaches (see Appendix 1). On consent, the main variation in approach related to deceased donation: Spain and Belgium operate ‘opt-out’ systems of consent, whereby the deceased person is presumed to have consented to donate organs unless they have specifically objected (see paragraph 3.53). It was noted, however, that in practice such systems differed less than might be imagined from the ‘opt-in’ system in the UK. In Spain, there is no requirement to express opposition to organ donation in any particular form, and hence it is standard practice to seek ‘consent’ from the family, on the basis that they will be well placed to know whether or not the deceased person was opposed to donation. In Belgium, the legal provisions governing consent for organ donation did not introduce a new social arrangement of ‘opt-out’, but rather codified existing arrangements whereby it had been standard practice in university hospitals to remove kidneys in the absence of formal objection. The legislation also introduced an explicit right of objection on the part of immediate family members. In the early years of the legislation, it was assumed that this right only arose if the family took the initiative to object; however, some centres felt that such a legal right should imply an obligation on the part of doctors explicitly to ask for their permission.

2.27 Legal provisions relating to consent on the part of living donors, however, do not appear to vary significantly between jurisdictions, perhaps reflecting the general ethical consensus as to the central role played by consent in such cases. Legislation relating to the donation of material for research (such as that set out in the US at federal level for research supported by federal agencies, or in the Spanish law on biomedical research) may list, for example, the kind of information that must be provided to a person before they consent, but little guidance is given on how much detail is required. Practical issues surrounding the amount and specificity of the information required for consent (particularly generic consent) to be legally valid are the subject of academic and professional disagreement across a range of jurisdictions.

Control and 'ownership' of bodily material

2.28 We have seen that a key legal and ethical concept governing the provision of bodily material to benefit others is that of consent on the part of the source of the material. The provisions regarding consent relate variously to the ‘taking’, the ‘storage’ and the ‘use’ of bodily material. A further question arises as to how far the person providing the bodily material may continue to influence the ‘use’ to which it is put: to what extent may controls, or conditions, be placed upon the future use of the donated material?

2.29 Within the UK, the scope of personal control varies significantly, depending on the type of bodily material being donated, and whether the person from whose body the material has come is living or dead.

■ Blood for therapeutic purposes is donated into a common pool.

---

150 The countries included in the review were Belgium, India, Iran, Israel, Spain and the US (at both federal and state level). The review focused on specific issues for each country, rather than attempting a detailed overview of every aspect of the legislation governing the donation of bodily material.


Living organ donors may specify the recipient (and indeed this is the usual reason for donating, although 'stranger donation' is now permitted).

Bone marrow donors may donate either to a named individual or to a common pool.

Gamete donors may donate either to named individuals, or to an unknown recipient. They may also currently specify the category of recipient, for example by restricting the use of their donated material to married couples or women under a particular age, although this ability to restrict use to recipients with particular characteristics is currently subject to review as to its compatibility with equality legislation. Gamete donors may also change their minds and withdraw their consent up until the point where the donated gametes have been 'used': this has been interpreted (in the context of donation for therapeutic purposes) as the point when an embryo created using the donor gamete(s) has been implanted in a woman.\textsuperscript{155}

Deceased organ or tissue donors (or those providing consent on their behalf) may have specified that their donated material should be used for the broad classes of 'transplantation' or 'research'. They cannot restrict their donation to a particular class of recipient, in the way currently permitted for gamete donors. However, requests that a deceased donation be directed towards a particular person may now exceptionally be endorsed, although donors cannot make this a condition of their donation.\textsuperscript{156}

2.30 The regulatory focus on consent enables the individual to have control over any such decision to donate (at least during life). At the same time it side-steps questions of whether, and to what extent, bodily material may be the subject of property rights. However, the increasingly 'transactional' nature of dealings concerning human bodily material (see paragraph 1.27) is putting the question of ownership and property rights over bodily material into the spotlight.

2.31 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. The rights of individual persons in connection with their own bodies are not legally those of 'property ownership', and individuals cannot be owned as property by others. However, the courts have, in certain circumstances been willing to recognise exceptions to this rule, particularly in relation to parts of bodies.\textsuperscript{157} It is now well established that where body parts "have acquired different attributes by virtue of the application of skill", then they may become 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.\textsuperscript{158} Thus any form of tissue that is 'processed' into new products in the way described in Chapter 1 (see paragraph 1.11) may be considered 'property' and may legitimately be sold (though not by the person who provided the source material).\textsuperscript{159} Moreover, courts are often prepared to protect the possession of body parts in the hands of third parties, such as the police or coroners, where this is in the service of some proper function.\textsuperscript{160}

2.32 The law in England and Wales, however, appears to be in a state of flux. In 2009, in the case of Yearworth, the Court of Appeal 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.\textsuperscript{161} 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

\textsuperscript{155} Evans v Amicus Healthcare Ltd & Others [2004] EWCA 727.
\textsuperscript{156} A request for a 'directed donation' may be considered if a named relative or friend of long-standing is in need of the organ, and a number of other criteria are met. An independent oversight group will decide whether or not the request should be granted, and priority will always be given to a patient in urgent clinical need. See: Department of Health (2010) \textit{Requested allocation of a deceased donor organ}, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_114803.pdf. This policy is agreed by all UK health administrations.
\textsuperscript{157} See, for example, AB v Leeds Teaching Hospital where Gage J stated that the "principle that part of a body may acquire the character of property which can be the subject of rights of possession and ownership is now part of our law": [2005] 2 WLR 358, at 394.
\textsuperscript{158} R v Kelly and Lindsay [1999] QB 621.
\textsuperscript{159} Human Tissue Act 2004, section 32: see also paragraph 2.34 below.
\textsuperscript{161} Yearworth and others v North Bristol NHS Trust [2009] EWCA Civ 37.
common law’s treatment of and approach to the issue of ownership of parts or products of a living human body”. The implications of this judgement, that bodily material may in some circumstances now legally be considered to be the property of the person from whom it came (that is, the source of the material), remain to be seen. We return, in Chapters 5 and 7, to the ethical, as well as legal, dimensions of ownership.

**Comparative material from other jurisdictions**

2.33 The snapshot review commissioned by the Working Party of legal provisions in a number of other jurisdictions (see paragraph 2.26 and Appendix 1) highlighted the wide range of potential approaches to the issue of the future control of donated material:

- Living kidney donation is very widely carried out on the basis of ‘directed donation’: indeed, as noted above, in the absence of material incentives to donate, the desire to benefit a known individual will appear to be the primary motivating factor in such a decision. Regulation differs however, in the extent to which it attempts to control individuals’ freedom to donate to those who are not known to them. Such donation is permitted in the UK and the US. India, on the other hand, explicitly limits living kidney donation to near relatives of those with a tie of “affection or attachment”: potential donors thus do not have the (legal) option of donating an organ, as a living donor, to a stranger. 162 This prohibition was introduced in 1994 in response to concerns about widespread organ trafficking; however, further regulation was introduced in 2008 in an attempt to clamp down on the many ways in which this requirement was being subverted, for example by impersonation or by the use of false marriage certificates. 163

- On gamete donation, completely opposite positions exist. In the US, directed donation for reproductive purposes is commonly allowed, with recipients often choosing their own donors (for example via direct advertisements). 164 In Spain, by contrast, recipients are not permitted to choose their own donors: this must be done, by law, by the medical team in order to preserve anonymity. 165

- The question of ownership, specifically of tissue, has been considered most comprehensively in the US courts. The case of Moore (also seen as influential in the UK) resulted in the decision that Mr Moore had no proper interests in the material excised from his body during treatment for leukaemia, and hence no entitlement to any profits from the commercialised cell-line subsequently developed from it. 166 Subsequent cases (Greenberg 167 and Catalona 168) upheld the principle that the sources of the material could neither benefit financially from subsequent commercial exploitation nor control the subsequent destination of the tissue. Both did so on the basis that any proprietary rights the sources of the material might initially have possessed had evaporated when the material was voluntarily handed over. However, it could be argued that, in taking this approach, these courts had recognised that such rights could indeed exist but had in these cases been voluntarily relinquished. Legal commentators have thus suggested that the US courts may indeed, in future, recognise individuals as having property rights in tissue detached from their own bodies, and that such rights could be retained if, for example, this was made explicit at the time of donation. 169 A rather different angle on questions of ownership and use is highlighted by Spanish law: while it is silent on the question of any property rights on the part of the source of the material, it states that biobanks are expected to share samples unless there is good reason to refuse,

---

162 The Transplantation of Human Organs Act 1994. [India]
165 Law 14/2006 on assisted human reproduction techniques, Article 6(4). [Spain]
166 Moore v Regents of the University of California, 793 P 2d 479 (Cal SC 1990).
thus implying that such samples should be seen as a common good. We return to this issue in Chapter 7 (see paragraph 7.51).

**Permissibility of commercial dealings in bodily material**

2.34 The issue of the permissibility of commercial dealings in human bodily material is distinct from questions of legal rights of property ownership. Where property rights are explicitly recognised (for example, where bodily material has been processed into a product through the application of skill), then such rights will typically include the entitlement to trade the product in commercial transactions. However, the absence of any clear property rights in other circumstances does not, in itself, mean that commercial dealings are unlawful. In the UK, various regulatory statutes explicitly forbid 'commercial dealings' in some circumstances, but are silent or permissive in others.

- The Human Tissue Act explicitly prohibits "commercial dealings in human material for transplantation" unless it has acquired the character of property "because of an application of human skill". This prohibition is given effect through the creation of an offence of giving or receiving a "reward" in connection with the donation of organs, tissue or blood, where the donated material is intended for the direct treatment of another. It does not cover reproductive material. "Commercial dealings" are not defined, as such, in the Act, but a reward is defined as "any description of financial or other material advantage". It is also explicitly stated that reimbursement in "money or money's worth" of any expenses or loss of earnings directly incurred by the donor as a result of making their donation is not prohibited. It is therefore an offence to offer to buy or sell a kidney; but it is not an offence for the NHS to reimburse any expenses incurred in the process of donating a kidney as a live donor.

- The Human Tissue (Scotland) Act similarly prohibits commercial dealings and the giving or receiving of a reward in connection with the supply of any part of a human body for transplantation. Again, reward is defined as "any description of financial or other material advantage", other than payment in "money or money's worth" to defray expenses and costs.

- Commercial dealings in organs, non-reproductive tissue and blood for any purposes other than transplantation are not covered by the HTA prohibition, and the Scottish provisions similarly relate only to transplantation. It would not, therefore, be unlawful under the Act to offer, or take, a payment in the UK when providing material for research for example. However, such payments do not appear to be widely offered to donors within the UK. One example of a benefit in kind is offered by medical schools who may cover cremation costs where a person has donated their whole body after death for the purposes of medical education and training.

- Under the Human Fertilisation and Embryology Act, "no money or other benefit shall be given or received" in respect of the supply of gametes or embryos unless authorised by directions issued by the HFEA. Current directions do not permit "money" to be given or received in exchange for eggs or sperm, whether these are donated for treatment purposes, or for research. However, the Directions do permit what are known as 'egg-sharing' arrangements, where women may be offered reduced fees for their private IVF treatment if they make some

---

174 It is however possible that a court would find any such arrangements as unenforceable, as contrary to public policy.
175 For example, the University of Bristol states that it will bear the cremation costs for a body which is donated to and used by its Centre for Comparative and Clinical Anatomy: University of Bristol (2010) *Donating your body to the Centre for Comparative and Clinical Anatomy, University of Bristol*, available at: [http://www.bristol.ac.uk/anatomy/documents/uobanat2.pdf](http://www.bristol.ac.uk/anatomy/documents/uobanat2.pdf).
176 Human Fertilisation and Embryology Act 1990, section 12(1)(e), as amended.
of their eggs available for another woman’s use. Donation of eggs in such circumstances may thus be regarded as resulting in indirect payment of considerable value. This approach has now been extended, at present on a one-off basis, to the ‘sharing’ of eggs for research.

Under the Surrogacy Arrangements Act 1985, it is an offence to broker a surrogate arrangement “on a commercial basis”. This prohibition does not apply to the commissioning parties or the surrogate mother; however, courts scrutinise what payments have been made when deciding whether to award parental rights to the commissioning parents (see below).

2.35 While the regulatory frameworks established under the Human Tissue Act, the Human Tissue (Scotland) Act and the Human Fertilisation and Embryology Act thus ban financial reward for donors in most circumstances, it is, however, recognised that donors may well incur expenses in the process of making a donation. Again, arrangements within the UK as to the reimbursement of expenses, the definitions of what is covered, and whether any expenses are capped, vary depending on the form of bodily material being donated.

At present, blood donors’ expenses are not routinely reimbursed; and indeed the infrastructure for donation is so extensive (for example through systems of work-place donation, and the ready availability of blood centres) that significant costs would not ordinarily be incurred. Such reimbursement would, however, be legal under the Human Tissue Act, and in fact some platelet donors are currently reimbursed for parking when they are donating at city centre sites.

Provision is made for the reimbursement of all expenses, including any lost earnings or welfare benefits, incurred by bone marrow and living organ donors. Guidance from the Department of Health makes clear that while the NHS is not legally obliged to make such payments, NHS trusts and PCTs should do so if the live transplant is permitted under the Human Tissue Act.

For gamete donors, the HFEA Code of Practice specifies that travel and other out-of-pocket expenses should be reimbursed in full but that lost earnings should be capped at £250 per cycle of egg donation or course of sperm donation. These rules on reimbursement are currently under review.

For surrogacy arrangements, the commissioning couple may pay for “expenses reasonably incurred”, but any other payments may jeopardise the making of a ‘parental order’ giving parental rights to the commissioning parents. In December 2010, however, the High Court did grant a parental order in a case where payments over and above expenses were paid to an overseas surrogate, noting that the welfare of the child (which in this case was held to lie in being brought up by the commissioning parents) was the paramount concern.

---


179 Surrogacy Arrangements Act 1985, section 2(2), as amended.


183 Human Fertilisation and Embryology Act 2008, section 54.  

184 Re L (A Minor) EWHC [2010] 3146 (Fam).
In the same way that the regulatory frameworks make provision for the reimbursement of expenses incurred by individuals when making a donation, it is also accepted that costs will inevitably arise for the intermediaries involved in facilitating donation and transplantation. The Human Tissue Act 2004 and the Human Tissue (Scotland) Act 2006 both exempt financial transactions necessary for such essential activities as transporting, removing, preparing, preserving or storing bodily material from the general prohibition on commercial dealings in connection with transplantation. The Human Tissue Act 2004, section 32(7); Human Tissue (Scotland) Act 2006, sections 17 and 20.

It is accepted that costs will inevitably arise for the intermediaries involved in facilitating donation and transplantation. The Human Tissue Act 2004 and the Human Tissue (Scotland) Act 2006 both exempt financial transactions necessary for such essential activities as transporting, removing, preparing, preserving or storing bodily material from the general prohibition on commercial dealings in connection with transplantation. The Human Tissue Act 2004, section 32(7); Human Tissue (Scotland) Act 2006, sections 17 and 20.

Payment for such activities is thus not considered to constitute 'commercial dealings'. Directions issued under the Human Fertilisation and Embryology Act 1990 similarly permit licensed fertility centres supplying donor gametes or embryos to other licensed centres to reclaim "the reasonable expenses incurred in the supply of the gametes or embryos" from the receiving centre.

By contrast with the above, there is no statutory restriction at all on payments made to healthy volunteers participating in first-in-human clinical trials: indeed the Association of the British Pharmaceutical Society argues that it is "right" for participants to be paid "more than just any expenses they may incur". The amount of the payment "should be related to the duration of residence on the unit, the number and length of visits, lifestyle restrictions and the type and extent of the inconvenience and discomfort involved. As a guide, payments should be based on the minimum hourly wage and should be increased for procedures requiring extra care on the part of the subject or involving more discomfort. Payment must never be related to risk." In other words, volunteers are financially remunerated. For many, the offer of such remuneration will be a key factor in their decision to participate.

There is clear consensus also at European level that financial reward (ie payment that goes beyond covering the costs incurred in the donation) for donors of any form of human bodily material is inappropriate. The EU Tissues and Cells Directive requires member states to "endeavour to ensure" that all donations from both living and deceased donors should be "voluntary and unpaid", while the Organ Directive states more forcefully that member states "shall ensure" that organ donations from both deceased and living donors are voluntary and unpaid. The Oviedo Convention and Additional Protocol require adherence to the principle that "the human body and its parts shall not, as such, give rise to financial gain"; the same phrase is used in the Council of Europe Recommendation from the Committee of Ministers in connection with biological materials donated for research. Allowance is generally made for the reimbursement of expenses, but there are significant differences in terminology in the different instruments, and with respect to different forms of bodily material, as to how such payments should be construed:

- The Organ Directive permits reimbursement that is "strictly limited to making good the expenses and loss of income related to the donation".
- The Tissues and Cells Directive (which covers both reproductive and non-reproductive tissue, hence cutting across HTA and HFEA boundaries) by contrast permits reimbursement "strictly limited to making good the expenses and inconveniences related to the donation". In contrast
to the Organ Directive, the Tissues and Cells Directive thus permits compensation for non-monetary as well as monetary losses.

- The additional protocol to the Oviedo Convention on transplantation (covering organs and non-reproductive tissue, but not blood and reproductive tissue) permits "compensation for loss of earnings or other justifiable expenses on the part of the donor".

2.39 The rather looser definition of what may be reimbursed in the Tissues and Cells Directive, permitting reimbursement for 'inconveniences', has led to significant disparity of interpretation within the member states of the EU (see paragraph 2.51).

2.40 The various European instruments also recognise in different ways that legitimate costs may be incurred by the organisations and individuals involved as 'intermediaries' between those providing bodily material, and those ultimately benefiting from it. The EU Tissues and Cells Directive states that member states should "endeavour" to ensure the procurement of tissues and cells is carried out on a non-profit basis while the Organ Directive is more prescriptive, stating that states "shall ensure" that procurement is carried out on a non-profit basis. The additional protocol to the Oviedo Convention on transplantation permits "a justifiable fee for legitimate medical or related technical services" and the explanatory memorandum to the Recommendation of the Committee of Ministers concerning biological materials notes that payments for "legitimate scientific or technical services rendered in connection with the use of such biological materials" would not be affected by the recommendation.

2.41 Both EU and Council of Europe instruments also promote the importance of equitable access to services, on the basis that systems that encourage voluntary and unpaid donation should ensure that those encouraged to donate may also have fair access to transplantation services should the need arise. The additional protocol to the Oviedo Convention, for example, requires that:

- a system exists to provide equitable access to transplantation services for patients; and
- procedures for distribution across participating countries take into account the principle of solidarity within each country.

The EU Organ Directive similarly highlights the importance of the "allocation of organs based on transparent, non-discriminatory and scientific criteria".

2.42 At international level, the distinctions between different forms of bodily material become rather more overt. The WHO Guiding Principles on human organ transplantation (which also apply to non-reproductive tissue) take a very similar approach to the UK and European instruments: they ban "any monetary payment or other reward of monetary value", while permitting the reimbursement of "reasonable and verifiable expenses incurred by the donor, including loss of income"). They also make reference to "societal recognition of the altruistic nature of cell, tissue and organ donation"; and call for the allocation of organs, cells and tissues to be "guided by

---

195 That is – with the aim of ensuring that there is not an 'underclass' of those donating bodily material, who do not themselves have access to health care when they need it. This approach contrasts with a system such as that being introduced in Israel, where those who promise to donate obtain enhanced access to a transplant should they need one in the future (see paragraph 2.48).
197 2010/45/EU, paragraph 20.
clinical criteria and ethical norms, not financial or other considerations”. The Declaration of Istanbul calls for the prohibition of ‘transplant commercialism’ (defined as where “an organ is treated as a commodity, including by being bought or sold or used for material gain”), while clarifying that “comprehensive reimbursement of the actual, documented costs of donating an organ” does not constitute purchase of the organ.198

2.43 By contrast, there is no similar international consensus statement concerning commercial dealings in eggs, sperm and embryos, and as discussed below, practice varies considerably around the world (see paragraphs 2.50 and 2.51).

Box 2.1: Terminology used with respect to „payment”: a summary

- The Human Tissue Act prohibits commercial dealings and rewards in connection with the provision of human material for the treatment of another. A “reward” is defined as “any description of financial or other material advantage”. However, the reimbursement in “money or money’s worth” of any expenses or loss of earnings directly incurred by the donor as a result of making their donation is explicitly not prohibited.
- The Human Tissue (Scotland) Act prohibits commercial dealings and the giving or receiving of a reward in connection with the supply of any part of a human body for transplantation. Reward is defined as “any description of financial or other material advantage”, other than payment in “money or money’s worth” to defray expenses and costs.
- The Human Fertilisation and Embryology Act prohibits money or other benefit in respect of the supply of gametes, unless explicitly authorised by Directions.
- The EU Tissues and Cells Directive requires Member States to “endeavour” to ensure that tissues and cells are donated on a voluntary and unpaid basis, and procured on a non-profit basis.
- The EU Organ Directive requires organ donations to be voluntary and unpaid and procurement to be on a non-profit basis.
- The Oviedo Convention states that the human body and its parts shall not, as such, give rise to financial gain.
- The World Health Organization’s Guiding Principles ban any monetary payment or other reward of monetary value.
- The Declaration of Istanbul calls for the prohibition of transplant commercialism, defined 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.
- The Association of the British Pharmaceutical Industry (ABPI) Guidelines for phase 1 clinical trials state that it is right to pay those who volunteer for phase 1 trials more than just any expenses they incur. Such payments should be based on the minimum wage, and should be increased for procedures requiring extra care on the part of the participant or involving more discomfort. Payment should never be related to risk.

2.44 As the preceding paragraphs demonstrate, a number of different terms are used to capture national and international concerns about the use of money in the context of human bodily material. To do justice to the complexity of these various terms as they are used in everyday life, while at the same time being as clear as possible for the purposes of this report, we propose the following terminology (see also the Glossary):

- Payment: a generic term covering all kinds of transactions involving money, and goods with monetary value, whether those transactions are understood as recompense, reward or purchases.
- Recompense: payment to a person in recognition of losses they have incurred, material or otherwise. This may take the form of the reimbursement of direct financial expenses incurred in donating bodily material (such as train fares and lost earnings); or compensation for non-financial losses (such as inconvenience, discomfort and time).
- Reward: 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. If reward is calculated as a wage or equivalent it becomes remuneration.
- Purchase: payment in direct exchange for a ‘thing’ (e.g. a certain amount for a kidney, or per egg).

We use this terminology throughout this report, with the exception of where we cite directly from others’ usage.

**Figure 2**

![Forms of payment diagram](image)

**Regulatory approaches in other countries**

2.45 Notwithstanding the existence of these international statements and declarations governing ‘reward’, ‘monetary payment’, and ‘benefit’ in connection with some forms of material (specifically organs and tissue), attitudes to the role of payment in the donation of bodily material differ significantly around the world, as highlighted by examples below from our snapshot review.

2.46 Iran is the one country in the world that explicitly renders reward for organs legal. Although Iran is widely described as promoting a ‘legal market’ in organs, the permitted payment is in fact described as a ‘social gift’, administered by a non-governmental agency.\(^\text{199}\) What we might want to see as a boundary between reward (for a person) and purchase (of a thing) is thus blurred. Donors or recipients may be put in touch with each other by the agency, or may approach it as a ready-formed pair. There are, however, strict controls on circumstances in which foreigners may be recipients: while foreign nationals may receive or donate an organ in an Iranian hospital, they must be ‘paired’ with someone of the same nationality, and the donor may not receive the payment.\(^\text{201}\) The amount paid, ten million Iranian Rials (approximately US$1,000), has not increased since the system was introduced in 1988;\(^\text{202}\) other benefits include free life-long health insurance and an annual donor-appreciation event.\(^\text{203}\) However, additional (illegal) payments are also frequently made between the parties involved and it is reported that the

---

199 See Appendix 1.
200 The scheme (i.e. the current system in Iran offering payment (as sacrifice gift) to living donors) was not set up by legislation: rather it is a service offered by a number of NGOs. The terms ‘social gift’ and ‘sacrifice gift’ are both used. (Professor Alireza Bagheri, personal communication, 19 February 2011).
Human bodies: donation for medicine and research

major part of the sum received by the donor now comes from the recipient. While such payments are against the law, their use appears to be openly tolerated with, for example, advertisements widely posted outside hospital entrances and not removed by hospital authorities.204

2.47 India explicitly prohibits all 'commercial dealings' in the context of living organ donation.205 The law is silent on whether reimbursement of actually incurred expenses would constitute commercial dealings, and at present no such reimbursement is provided.206 Although the prohibition on commercial dealings was introduced in 1994, in an attempt to tackle widespread organ trafficking, it proved very difficult to enforce: the 'authorising committees' responsible for reviewing donations were expected to cover as many as 700 cases a year; 'middlemen' brokering illicit transactions often held jobs with the hospital where the surgery was due to take place and could coach donors and recipients on how to 'beat the system'; and hospitals and transplant surgeons appeared to turn a blind eye to these and other problems.207 In an attempt to deal with these problems, the 1994 Act was amended in 2008 to increase the resources and independence of the authorising committees: they are now expected to review around 25 cases a year; doctors from the transplant team are excluded from membership; and better records are required.208 There is little information, as yet, as to how well these new measures are working. In 2009, a regulatory review committee also recommended that benefits such as coverage of medical expenses, medical insurance and travel concessions should be introduced for living donors, and these are currently being considered.209

2.48 Israel prohibits all 'rewards' for organs, except for specified categories.210 These permitted categories include payment for burial and transportation costs after death, a certificate of recognition (providing free entrance to national parks and nature reserves) and "allowable reimbursements".211 Others might regard these 'reimbursements' as a form of reward; they include up to 40 days' sick leave, up to one week's stay in a hotel after the operation and capped contributions to life, health and employment insurance for up to five years.212 Israel has also very recently introduced a "priority points" system, under which those who consent in advance to donate after their deaths, or those who donate an organ during their lifetime, earn points to increase their own priority (or that of a parent, sibling, child or spouse) for an organ should they need one in the future.213 The degree of priority depends on the circumstances of donation: a living donor of an organ will obtain "maximum" priority for themselves or their close family members in need of an organ, while holding a donor card will lead to "priority" for the card-holder and "second priority" for their family members.214 However, it should be noted that allocation criteria are categorised as 'status 1' (medical criteria such as degree of medical need and compatibility) and 'status 2'; and these priority criteria will only be relevant as 'status 2' considerations. Policy officials therefore do not expect the new system to have a major effect on the allocation of organs, but are optimistic that it will encourage more people to sign donor cards.215

208 Transplantation of Human Organ (Amendment) Rules 2008. [India]
210 Organ Transplant Act 2008, section 2(3). [Israel]
211 Organ Transplant Act 2008, Articles 30, 23 and 22 respectively. [Israel]
212 Personal communication via Dr Kathy Liddell, 28 November 2010.
213 Provision for such a scheme is made under Article 9(b)(4) of the 2008 Act.
215 Personal communication via Dr Kathy Liddell, 28 November 2010.
2.49 In its National Organ Transplantation Act 1984 (NOTA), the US prohibits at federal level any "valuable consideration" for organs, defined to include "kidney, liver, lung, pancreas, bone marrow, cornea, eye, bone and skin, and any other human organ or part thereof". Reimbursement of donors' expenses is, however, permitted. In the light of the length of waiting lists for donated organs, a number of attempts have been made at both state and federal level to introduce changes to NOTA, one example being the Specter Bill that sought to redefine valuable consideration to permit reward in kind offered by federal, state and local governments. To date, all such attempts have been unsuccessful. There is, however, a current legal challenge to the inclusion of bone marrow in the definition of 'organ' by the organisation Moremarrowdonors.org, which would like to introduce a system of payments in kind, such as college scholarships, housing allowances or donations to charity, to encourage more bone marrow donors to come forward. The case argues that the prohibition on the payment of valuable consideration for bone marrow is unconstitutional, and is arbitrarily and unjustifiably blocking US citizens' liberty to pay bone marrow donors for their trouble and discomfort. At the time of writing the decision on this case is still awaited. While bone marrow is included within the NOTA provisions, blood plasma is treated as a separate matter and payments (reported as being between $20 and $30 per donation, although this will vary from clinic to clinic) are permitted.

2.50 The US position on payment for gametes contrasts sharply with that taken on organs: many state laws are silent (hence permissive) on this issue and payments of $5,000 to $10,000 for eggs for fertility treatment are commonly made. To all intents and purposes, the transaction is a purchase. While guidelines from the American Society for Reproductive Medicine (ASRM) state that payments over $5,000 require justification and those over $10,000 are not appropriate, nevertheless amounts offered for eggs are reported to go as high as $50,000 where donors have specific physical, cultural or intellectual traits (examples cited include good-looking Ivy-League students, or East Asian or Jewish women). Sperm donors on the other hand may obtain in the order of $75, although the recipient may have to pay $250 to $400 to the clinic. The amounts paid to those willing to provide eggs for treatment contrast sharply with those providing eggs for research where payment is much rarer. Guidelines published by the National Academy of Sciences permit only the reimbursement of expenses incurred in donating,

---

216 The Act applies to transfers of human organs obtained from both living or deceased donors for transplantation. It does not cover material donated for research.
217 "Reasonable payments" associated with removal, transportation, implantation, processing, preservation, quality control, storage, travel, housing, and lost wages are excluded from the definition of "valuable consideration": 42 USC 274e(c)(2).
220 Plasma Protein Therapeutics Association, personal communication, 1 August 2011.
such as costs "associated with travel, housing, child care, medical care, health insurance and actual lost wages".  

2.51 **Spain**, like the UK, is subject to the EU Tissues and Cells Directive which requires donation to be "voluntary and unpaid", but which permits reimbursement that is "strictly limited to making good the expenses and inconveniences related to the donation" (see paragraph 2.38). However, in the context of gamete donation, Spanish law has interpreted these requirements rather differently from the UK. The National Commission of Assisted Reproduction currently sets the rate of compensation at €916, based on an estimate of the amount of work time lost (38 hours at €15 per hour), travel expenses (€270), meals (€40), and discomfort for hormone injections (€36).  

While the total figure is therefore clearly presented as compensation for monetary and non-monetary losses, it is often depicted in the form of a reward.

### Safety

2.52 Finally, a key factor in all regulatory schemes is that of safety. Safety concerns relate both to potential harm to the individual who is either providing bodily material as a live donor or taking part in a first-in-human trial; and to the future recipients of donated material.

2.53 We have alluded above (see paragraph 2.24) to the protections set out in both EU and domestic legislation with respect to the safety and well-being of living donors. More detailed requirements are set out in domestic guidance, for example through the HTA Code of Practice which requires that potential organ donors undergo a full assessment of their medical suitability to donate before referral for scrutiny by the HTA itself.  

Similarly, bone marrow donors must receive a full medical 'work-up' to determine whether they are suitable for the procedure, and the HFEA requires that clinics should take medical and family histories before permitting prospective donors to provide gametes. The National Blood Service lists a number of reasons why people should not become blood donors because of the risks to their own health, including weighing less than 50 kilograms, currently taking antibiotics, or waiting for hospital treatment; and requires potential donors to fill in a 'donor health check' questionnaire and provide a drop of blood to check that they are not anaemic, before going ahead.

2.54 Safety factors are clearly also central to the regulation both of first-in-human trials and, more widely, of any research involving human participants. Domestic and EU regulations alike make explicit reference to acceptable levels of risk to research participants. First-in-human clinical trials may only take place if the anticipated therapeutic and public health benefits justify the risks; and in addition to the requirements for ethical review (see paragraph 2.12), trials must be authorised by the MHRA before they may go ahead. International standards, in the form of "Good Manufacturing Practice" (GMP) for all trial medicines and "Good Clinical Practice" (GCP) standards must be met in all trials of medicines, with provision for these to be inspected by the MHRA. GMP ensures that medicinal products are produced and controlled to the

---


227 Professor Antonio Pellicer, personal communication, 26 July 2011.


quality standards appropriate to their intended use and as required by the marketing authorisation or product specification. GCP comprises a set of internationally recognised ethical and scientific quality requirements which must be observed in the design, conduct, recording and reporting of clinical trials involving human subjects. The ‘TOPS’ database (‘The Over-Volunteering Prevention System’) provides the opportunity for trial centres to record when healthy volunteers take part in trials anywhere in the UK, to help prevent people from participating too often.236

2.55 At Council of Europe level, the Oviedo Convention sets out the principle that any medical research on humans is permissible only if "there is no alternative of comparable effectiveness to research on humans" and if "the risks which may be incurred by that person are not disproportionate to the potential benefits of the research".237 The Declaration of Helsinki states that "medical research involving human subjects may only be conducted if the importance of the objective outweighs the inherent risks and burdens to the research subjects" and that "physicians may not participate in a research study involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed".238

2.56 In order to promote the safety of the recipients of donated material, the EU Directives on organs, tissues and cells, and blood respectively all call for a unified framework for quality and safety to be established in all member states, and for all material to be traceable from donor to end-recipient.239 The WHO Guiding Principles on organ and non-reproductive tissue similarly require the implementation of quality systems, including systems for traceability and adverse event reporting. When the Working Party met with a number of regulators (see paragraph 2.70), the crucial role played by these safety and traceability requirements was emphasised by several of those present, despite concerns about the associated bureaucratic demands that might act as a disincentive to researchers, or the potential burden on the provider of material such as the requirement to submit to screening and intrusive questioning.240

2.57 A key safety concern is that of minimising the risks of transmitting disease from donor to recipient, in the case of both living and deceased donation. Hence, where bodily material is donated either in life or after death, enquiries are made into a potential donor’s social, behavioural and medical history. Where the donor is dead, these enquiries are addressed to their GP and family members. In addition to these safety precautions at the time of donation, it is also important to ensure that bodily material can later be easily traced and linked: donors after death can, for example, donate multiple organs or tissues, and if there is a problem with one transplant, it is important for medical reasons to be able to trace other recipients of material from the same person.241 While tissue is ‘quarantined’ for a period after donation (in contrast to organs which are transplanted as quickly as possible), thus reducing the risk of infection being

---

239 It is beyond the scope of this report to summarise how these requirements are implemented in the UK; however, detailed requirements relating to the safety of donated materials are set out in the Code of Practice published by the Human Fertilisation and Embryology Authority and in the Human Tissue Authority licensing requirements under the Quality and Safety Regulations (see: Human Fertilisation and Embryology Authority (2009) Code of practice, available at: http://www.hfea.gov.uk/docs/8th_Code_of_Practice%282%29.pdf; Human Tissue Authority (2010) Licensing under the Quality and Safety Regulations, available at: http://www.hta.gov.uk/licensingandinspections/licensingunderthequalityandsafetyregulations.cfm).
240 Meeting held with regulators on 23 June 2010 – see Appendix 1.
identified too late, nevertheless errors involving tissue may have more extensive implications given the very large number of potential recipients. Moreover, in the case of tissue recipients, the donated material may in some cases be used for procedures to improve quality of life, such as cartilage transplants, rather than life-saving procedures: in such situations patients may well have a different approach to the degree of risk they are willing to accept.

2.58 Where material is donated during life, there are additional reasons for ensuring traceability. Where material is donated for research purposes, clinical findings that may affect the donor’s own health may emerge at a later stage, and where material such as blood is donated for therapeutic purposes, routine safety testing may produce results that are significant for the donor’s own health care. Similar concerns arise where reproductive material is donated. However, as noted below (see paragraph 2.74), additional, very different, reasons for traceability now exist in the case where a child is born as a result of egg or sperm donation: information about the donor must be retained so that any child born as a result of the donation can access it at the age of 18 years. These ‘social’ reasons for traceability clearly have rather different implications from the medical reasons described here.

**Licensing**

2.59 Many of the regulations discussed above imply authorised bodies that are able to oversee the transaction at issue. Between the individuals concerned (donors, clinicians, researchers and so forth), and the protocols and regulations that govern their behaviour, are intermediaries of another kind: the institutions, clinics, hospitals, and research laboratories that carry out procedures. Another area of regulation is thus concerned with the oversight of such institutions, which is achieved within the UK by a licensing regime: treatment or research using donated materials may only proceed under licence. The role of licensing bodies is thus highly influential in determining the impact of regulation on day-to-day practice.

2.60 Under the Human Tissue Act 2004, a number of activities are only lawful in England, Wales and Northern Ireland if licensed by the HTA. These include:

- Carrying out an anatomical examination;
- Making a post-mortem examination;
- Removing organs and tissue from a deceased person (other than for the purposes of transplantation where no licence is required);
- Storing organs and tissue from a living or deceased person for the treatment of patients, or for research (other than for a specific ethically approved research project).

On behalf of the Scottish Government, the HTA also licenses organisations in Scotland that procure, store, test, process, distribute, import or export human tissues or cells that are intended to treat patients.

2.61 The Human Fertilisation and Embryology Act 1990 similarly sets out a number of activities that are only lawful if licensed by the HFEA. These include storing gametes or embryos, creating embryos in vitro, and using sperm, eggs or embryos in fertility treatment services. Research activities are licensed separately from treatment services, and centres that both undertake research and offer treatment services require separate licences for each activity.

---

242 See, for example, NHS Blood and Transplant (2007) *Tests on your blood*, available at: [http://www.blood.co.uk/pdf/tests_on.pdf](http://www.blood.co.uk/pdf/tests_on.pdf), where it is stated: “If your blood gives a positive test result we will inform you and offer you appropriate advice. If the result is significant to your health you will be asked to discuss the results with one of our doctors and, with your permission, we will arrange a referral to your own doctor or a specialist.”

243 As amended by the Human Fertilisation and Embryology Act 2008.

244 Other than partner-donated sperm that has not been processed or stored.
The growth of regulatory frameworks

2.62 The historical events lying behind the development of these various regulatory frameworks – both within the UK and on an international basis – can be broadly divided into two categories: response to medical accident or scandal; and response to the challenges of new technologies.

Response to medical accident or scandal

2.63 The regulation of medicines has evolved gradually over the last century, as the production of medicines moved from individual pharmacists’ premises to mass production, and from an emphasis on following old ‘recipes’ to the development of new medicines based on pharmaceutical research. This gradual process leading towards the current system of mandatory testing and licensing has, however, been given extra stimulus by highly publicised medical accidents such as: the marketing of ‘elixir sulfanilamide’ (a liquid form of an existing drug, inadvertently containing a poison in the solution) in the US in 1937;245 and the dangerous effects of thalidomide in the UK in the 1950s and early 1960s. In the UK, the outcry over thalidomide led to the setting up of the Committee on Safety of Drugs in 1963, and a new system of licensing under the Medicines Act 1968.246 The Committee on Safety of Drugs subsequently became the Committee on Safety of Medicines and in 2005 merged with the Medicines Commission to become the Commission on Human Medicines (CHM).

2.64 The CHM’s main role is to provide independent scientific advice on the safety, quality, and efficacy of new medicines.247 The Commission was not initially involved in the appraisal of clinical trials, but gained this role in 2007 after the serious adverse reactions suffered by six volunteers taking the experimental compound TGN1412 at Northwick Park hospital in 2006. A series of recommendations made as a result of the subsequent inquiry into the events at Northwick Park aimed to improve the reduction and management of risk, and emphasised the importance of good communication with RECs at an early stage.248 The CHM may now be requested by the MHRA to offer expert advice on first-in-human trials where this is thought necessary.249

2.65 A similar history of ‘scandal’ lies behind much of current regulatory structure governing organs and tissue in the UK. The Human Organ Transplants Act 1989 was enacted in order to prohibit the sale of organs, in direct response to allegations that kidneys from paid donors had been transplanted at a London hospital.250 The Human Tissue Act 2004, which replaced both the 1989 Act, and other earlier legislation, retained this policy of not commercialising organs. However, as noted earlier in this report, the 2004 Act was not just a consolidation measure: it was also a response to concerns about inappropriate organ and tissue retention at Alder Hey Hospital in Liverpool, Bristol Royal Infirmary, and other NHS hospitals.251 The public outcry about the retention, ostensibly for research purposes, of bodily material from dead children, without valid consent from the parents, or on the basis of consent given without proper

245 See the FDA website for a history of the ‘sulfanilamide disaster’: http://www.fda.gov/AboutFDAWhatWeDo/History/ProductRegulation/SulfanilamideDisaster/ucm2007257.htm.
249 The decision to refer trial applications to CHM will be based on an assessment of risk factors. For further information on the circumstances where the CHM may be consulted for advice, see: Medicines and Healthcare products Regulatory Agency (2009) Applications first time in man (FTIM) trials with novel compounds, available at: http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/ClinicalTrials/Commonissues/index.htm.
understanding of how much material was being taken, led to a new focus on the need for explicit consent before any material could be retained and used. This represented a significant shift from the earlier approach in the Human Tissue Act 1961, which relied on 'lack of objection' as a legal basis for bodily material to be used after death for therapeutic purposes, medical education or medical research, and which furthermore included no penalty for transgression.252

2.66 The first WHO Guiding Principles on human organ transplantation were similarly developed as a result of World Health Assembly concerns about "trade for profit in human organs" in 1987.253 The Principles were adopted in 1991, and emphasised the importance of no payment for organs and tissues, with the aim of avoiding exploitative or divisive practices; they also encouraged countries to become self-sufficient. The revised Principles, adopted in 2010, while retaining the ban on commercialisation, responded in addition to scientific and social changes (see paragraph 2.69).

2.67 Concern about 'trafficking' also led to the production in 2009 of a joint study on the issue by the Council of Europe and the United Nations.254 This report highlighted the important distinction to be made between trafficking in people for the purpose of organ removal, and trafficking in organs, tissues and cells themselves. Trafficking in human beings for the purposes of removing organs is covered by existing Council of Europe and United Nations conventions on human trafficking; by contrast, there is no international agreement on what constitutes 'trafficking' in organs, tissues or cells. The joint study called for such a definition to be agreed at an international level, and suggested that the starting point for any such definition should be "the idea that any organ transaction outside the national systems for organ transplantation should be considered organ trafficking".255 The year before, the Declaration of Istanbul had condemned organ trafficking, which it defined as "the recruitment, transport, transfer, harbouring, 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."256

Response to scientific development

2.68 In contrast to the regulation of new pharmaceutical compounds, and dealings in human organs and tissues, regulation governing reproductive materials has evolved in response to technological and medical developments: in particular the birth in 1978 of the first 'test-tube baby' Louise Brown.257 However, it took more than a decade until the Human Fertilisation and Embryology Act was passed in 1990, and hence the practice of infertility treatment using IVF techniques became well established before the regulatory structure came fully into force.258 By the time the 1990 Act was implemented, the use of donor gametes for IVF treatment was also well-established: the use of donor sperm had been possible for many decades, while egg donation was developed in the 1980s.

2.69 As we note earlier (see paragraph 2.66), scientific and social developments also played a contribution in the decision to revise the WHO’s Guiding Principles for organ and tissue

---

258 There was, however, an Interim (Voluntary) Licensing Authority which was established in 1985 following the publication of the Warnock report. This operated until the HFEA was established through legislation passed in 1990.
transplantation. In 2004, the World Health Assembly felt it appropriate for the Principles to be updated to respond to "current trends in transplantation, particularly organ transplants from living donors and the increasing use of human cells and tissues".\(^{259}\) In addition to setting out requirements that aim to ensure the voluntary nature of donation, prohibit the sale or purchase of cells, tissues and organs, and promote high standards of safety and quality of donated material, the Principles also state that "the maximal development" of deceased donation programmes is to be promoted because of the risks inherent in living donation.

**Issues arising in current regulation**

**Issues raised by individual UK regulators**

2.70 The Working Party met with representatives from a number of regulatory bodies, from the pharmaceutical industry, and from the National Research Ethics Service (NRES),\(^{260}\) to discuss both the background to regulation in their particular field, and their current focus and concerns.\(^{261}\)

2.71 The HTA told us that their primary concerns are to ensure that consent to donation is voluntary, and that donations are made on the basis of 'altruism' and the 'gift relationship'. (We return to the question of how these terms are understood in Chapters 4 and 5.) The main ethical concerns for the HTA relate to the possibility of coercion and the risks inherent in live donation; and the key ethical principle underpinning their work is that the person making the donation not only has the information necessary to make their decision but also understands it.

2.72 For 'first-in-human' trials, those working in the field highlighted the difficulties inherent in ensuring 'consent' is meaningful in circumstances when the risks to humans of the new compound are unknown and possibly unknowable (and indeed where the substances may, by their nature, be becoming increasingly specific for pharmacological targets in humans and therefore not active in other animal species). This issue is of particular concern given that, even in circumstances where the nature of a risk is well established, difficulty is often experienced in communicating that risk to an individual in a way that is meaningful to them.

2.73 Both those involved in carrying out pharmaceutical research and the representative of the NRES also highlighted how researchers and RECs alike struggle with ethical concerns around monetary compensation for volunteers.

2.74 The HFEA noted two areas where the regulation of reproductive material raises rather different issues from those generated by other kinds of donation. The first relates to the possibility of a future relationship with a person genetically related to the donor: donation of gametes or embryos clearly has the potential to result in a child, a 'third party' in the transaction. Donation is permitted both to known and unknown recipients; moreover, children conceived after 1 April 2005 as a result of donated gametes are entitled to ask for identifying information about their donor once they reach the age of 18 years.\(^{262}\) Thus, depending on the circumstances of donation, the date of the donation, and the individual decisions of the parents bringing up children conceived using donated gametes, children's experiences may vary from a close personal relationship with their donor (for example the child's social 'aunt' who donated eggs to her sister and hence is the genetic mother), to ignorance that they are donor-conceived.

---


260 NRES is part of the National Patient Safety Agency, and works to protect research participants and facilitate and promote ethical research. It also supports the work of RECs.

261 Meeting held with regulators on 23 June 2010 – see Appendix 1.

Similarly, ‘anonymous’ donors who have donated since 2005 have to accept that they may be contacted in 18 years’ time by their genetic child.

2.75 The second point raised by the HFEA was the mainly private sector nature of infertility treatment. Initial development of infertility clinics in the 1970s and 1980s took place largely in the private sector, and although infertility treatment is now available within the NHS, provision has remained patchy.\(^{263}\) One implication of the private nature of much infertility practice is that there is no national framework either for recruiting egg and sperm donors, or for allocating donated gametes, and hence approaches vary between clinics. Another is that the transactions involved in undergoing fertility treatments are already on a commercial footing, insofar as fees will be payable to the clinic for its services, even though financial reward for the donor of gametes is forbidden. We return to the issue of what is ‘public’ as opposed to what is ‘private’ in Chapter 4.

**Issues of common concern in regulation**

2.76 A number of common issues were raised with us both by regulators and by respondents to our public consultation, and these are briefly highlighted in Box 2.2. While we cannot aim to respond to all these issues in this one report, we return to many of the concerns in more detail in later chapters.

---

**Box 2.2: Issues of regulatory concern**

**Consent**
The main regulatory concerns about consent that arise in the context of the donation of human bodily material or volunteering for a first-in-human clinical trial relate to factors that may potentially undermine the validity of the consent, and to the question of the scope of the consent sought:

- On validity of consent, 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 considering donating material or participating in a first-in-human trial, thus invalidating their consent. RECs currently struggle with this issue when asked to approve payments to participants in first-in-human trials. Similar concerns about ‘undue influence’ arise in connection with the possibility of coercion within the family, where one family member is being encouraged to donate bodily material to help another.

- In terms of the scope of the consent for research, is it appropriate to encourage the use of generic consent over specific consent, despite the inevitably imperfect information that can be given to the donor at the time consent is sought? And if so, is it more appropriate to develop systems of broad consent, with ongoing commitment to contact between researchers and donors; tiered or fettered consent where particular ‘opt-outs’ are available; or simple blanket consent, with no limits and no future relationship?

**Recompense**
The rather different rules applied to recompensing losses incurred in donations of different forms of bodily material (see paragraph 2.35) highlight a number of difficult ethical issues in this area:

- What should recompense be provided for? Should such recompense relate only to receipted expenses, such as travel costs or lost earnings, or should non-financial ‘losses’, such as inconvenience or discomfort, be recompensed in some way? The EU Tissues and Cells Directive permits such recompense, while the EU Organ Directive does not.

- If lost earnings are to be reimbursed, why not remuneration for a person’s time in other circumstances?

- Why is it acceptable to offer benefits in kind, such as ‘egg-sharing’ to egg donors, but not the equivalent monetary value?

- Given that most, if not all, of those involved as ‘intermediaries’ between the donor and recipient of material, will be remunerated for their work, is it just that donors cannot be rewarded?

**Role of living organ donors**

Living kidney donation is positively encouraged in the UK and elsewhere, and has become a significant source of kidneys for transplantation (see paragraph 1.9). However, both the Oviedo Convention and the WHO Guiding Principles emphasise that deceased donation is to be preferred where possible. Given the risks to the donor inherent in living organ donation, how far should regulatory bodies go in actively encouraging living donation?

---

\(^{263}\) In a recent survey of the provision of IVF services by PCTs, it was found that, of the PCTs which offer IVF to patients, 39 per cent offer one cycle of treatment; 26 per cent offer two cycles; and 27 per cent offer three. See: All Party Parliamentary Group on Infertility (2011) *Holding back the British IVF revolution? A report into NHS IVF provision in the UK today*, available at: [http://www.infertilitynetworkuk.com/uploadedFiles/InfertilityAwareness/appg%20IVF%20report.pdf](http://www.infertilitynetworkuk.com/uploadedFiles/InfertilityAwareness/appg%20IVF%20report.pdf), part 4.
Traceability
While traceability requirements have clearly been adopted in order to enhance the safe use of donated material, they can nevertheless in their turn raise ethical challenges, for example:

- the potential distress caused to the family of a deceased donor if hitherto unknown information about their relative’s past lifestyle comes to light;
- implications for the family if information about genetic diseases is revealed;
- whether an organ or tissue that has already been transplanted should be removed if information that affects its suitability as a transplant later emerges.