

# **Agreement between Crown Office and Procurator Fiscal Service and The Scottish Donation and Transplant Group In regard to Organ and Tissue Donation**

**October 2014**

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# Agreement between Crown Office and Procurator Fiscal Service and the Scottish Donation and Transplant Group\* in regard to Organ and Tissue Donation

\* Formerly Scottish Transplant Group

## Introduction

Successful organ transplants can be lifesaving, and for many people organ and tissue transplants are the most effective form of treatment. However, many people are unable to benefit from a transplant because of a shortage of donated organs and tissues.

In the UK, around 1000 people a year die while waiting for an organ to become available. Recognising therefore that unnecessary deaths occur every year in the UK the UK Organ Donation Taskforce produced its first report in January 2008<sup>1</sup> with 14 recommendations designed to remove existing barriers to donation, and to make organ donation a usual part of all end-of-life care in every appropriate case. Implementation of these recommendations in Scotland had high-level Government support, acknowledging that Scottish donation rates have generally been the lowest in the UK.

Two of those recommendations are particularly relevant to this Agreement.

Recommendation 14: 'The Department of Health and the Ministry of Justice should develop formal guidelines for coroners concerning organ donation.' In Scotland, it was considered that this recommendation had been achieved already, because of the existence since 2004 of the Agreement between the Scottish Transplant Group and the Crown Office & Procurator Fiscal Service. It underlines the need, however, to ensure that the Agreement is kept up-to-date.

The other recommendation is Recommendation 3, the main element in which is:

*“Urgent attention is required to resolve outstanding legal, ethical and professional issues in order to ensure that all clinicians are supported and are able to work within a clear and unambiguous framework of good practice.”*

The issues to which recommendation 3 particularly refers are those associated with donation after circulatory death (DCD). As a result of the development of DCD programmes in Scotland there has been a year on year increase in this type of donation. The increasingly important contribution which DCD has been making to the number of organ donors in Scotland has served to underline the importance of resolving the legal, ethical and professional issues associated with the process.

In May 2010, the Chief Medical Officer for Scotland issued guidance<sup>2</sup> to NHS Scotland to clarify the legal issues relevant to DCD in the form of CMO Letter SGHD/CMO (2010)11 on 3 May 2010 (as clarified in CMO Letter (2012)08 of 23 July 2012)<sup>3</sup>. Its release paralleled similar guidance issued in November 2009 to the rest of the UK. In essence, the Scottish guidance clarified the application of the

principles of the Adults with Incapacity (Scotland) Act 2000<sup>6</sup> to organ donation. Further clarification on these issues was provided through a consensus event on DCD organised by the 4 UK Health Departments and NHS Blood and Transplant (NHSBT) held in June 2010. The report on the event, *Donation after Circulatory Death*, was published in December 2010<sup>8</sup>.

## **Diagnosis and Confirmation of Death**

Prior to the advent of modern Intensive Care techniques, the diagnosis of death was relatively simple. Death was diagnosed at the cessation of circulation. The advent of long-term ventilation techniques in the 1950s meant inadequate ventilation no longer immediately led to circulatory death. With the advent of these techniques, case series of patients with profound irreversible apnoeic coma began to be described.

The current UK consensus is that “Death entails the irreversible loss of those essential characteristics which are necessary to the existence of a living human person and, thus, the definition of death should be regarded as the irreversible loss of the capacity for consciousness, combined with irreversible loss of the capacity to breathe.” (*A Code of Practice for the diagnosis and confirmation of death. Academy of the Royal Medical Colleges 2008*)<sup>4</sup>.

In the UK, death can be diagnosed after brain stem death or after circulatory death.

In the recent past organ donation has largely depended on donors being pronounced dead following brain stem death testing while still on mechanical ventilation in an intensive care unit. This is termed Donation after Brain Stem Death (DBD), having previously been known as heart beating donation.

However, more recently, partly because of a shortage of organs from DBD donors, there has been a ten-fold increase in the number of Donation after Circulatory Death (DCD) donors in the UK. DCD donation was previously known as non-heart beating donation or donation following cardiac death.

## **Donation after Brain Stem Death**

The irreversible cessation of brain-stem function, whether induced by intra-cranial events or the result of extra-cranial phenomena such as hypoxia, will produce this clinical state, and irreversible cessation of the integrative function of the brain-stem therefore equates with the death of the individual and allows the medical practitioner to diagnose death. For organ retrieval to be legal and acceptable, the certification of brain stem death must be sufficiently rigorous to give those close to the deceased total confidence that death has occurred before any procedures relating to organ or tissue donation are commenced. Certification of brain death must be completed by two senior doctors who are independent of the transplant teams and can only take place after rigorous preconditions are met. Further protection is given by the terms of section 11(4) of the Human Tissue (Scotland) Act 2006<sup>5</sup>, which provides that the surgeon proposing to remove body parts for the purpose of transplantation must be satisfied that life is extinct.

## Donation after Circulatory Death

Donation following circulatory death takes place after death has been diagnosed from the irreversible cessation of the heart. Kidneys, liver, pancreas and lungs from DCD donors can be successfully transplanted with graft survival results similar to those organs retrieved from DBD donors.

DCD is grouped using the categorisation agreed at Maastricht in 1995 (amended 2003) as follows:

I	Brought into hospital dead
II	Unsuccessful resuscitation
III	Awaiting Cardiac Arrest (i.e. following withdrawal of life-sustaining treatment)
IV	Cardiac Arrest in a Brain Stem Dead donor
V	Cardiac Arrest in a Hospital Inpatient

In terms of this classification, all of the current Scottish DCD programmes come within Category III, with the exception of a pilot Category II programme in NHS Lothian.

## The Law

**Until the point at which life is pronounced extinct**, the relevant legislation is the Adults with Incapacity (Scotland) Act 2000 (AWI). The AWI Act requires that any interventions in relation to an incapacitated adult observe certain general principles. These are that the intervention benefits the adult, and that such benefit could not reasonably be achieved without the intervention. The intervention should always be the least necessary to achieve the end.

The guidance issued as CMO letter (2010)11 indicates that the concept of 'benefit' is likely to be wider than the adult's immediate medical situation, and can reasonably be interpreted as permitting something that the adult could reasonably be expected to have chosen to do if capable, even though the action was of a gratuitous or unselfish nature. If, having weighed up all of the factors relevant to the person's situation, and consulted their family and friends, it is decided that a particular action or actions that will facilitate DCD is for the person's benefit, then it may be carried out. This means that a range of non-invasive actions can be taken that would pave the way for DCD.

The position regarding invasive procedures that might be undertaken prior to death with a view solely to better preserving the person's organs for transplantation would count as medical treatment and are therefore governed by section 47 of the AWI (Scotland) 2000 Act. It provides that medical treatment can only be undertaken if it is intended to safeguard or promote the physical or mental health of the adult. As part of the process of implementing Recommendation 3 of the UK Organ Donation

Taskforce's report, the Government will undertake a consultation in the future on the possibility of permitting more invasive procedures to preserve the adult's organs for transplantation, once the clinicians and family had agreed that further treatment would be futile. The consultation will also explore the type of authorisation considered necessary to support this approach.

**Once death has been confirmed**, the relevant provisions of the Human Tissue (Scotland) Act 2006 apply and must guide the next steps when organ donation is to take place.

The 2006 Act is based on the concept of authorisation. As explained in paragraph 8 of the "Guide to the Implications of the Human Tissue (Scotland) Act 2006", issued as HDL (2006)46 on 20 July 2006<sup>7</sup>, 'authorisation' is the expression of the principle that people have the right to specify, during their lifetime, their wishes about what should happen to their bodies after their death, in the expectation that those wishes will be respected.

This emphasis on the autonomy of the individual is also one of the underlying principles of the AWI legislation. It therefore underlines the importance of making sure that, where people's wishes are known, practical arrangements made around death the time of death are designed to ensure those wishes can be fulfilled.

### **NHS Organ Donor Register**

Any adult or child aged 12 and over, who is able to make their own decisions can give authorisation for their organs or tissue to be donated after death for the purpose of transplantation. Signing up to the NHS Organ Donor Register counts as a form of authorisation under the Human Tissue (Scotland) 2006 Act. Similarly, simply telling someone also counts as a form of authorisation under the Act. Many people who have not put their names on the Register still carry an organ donor card, and this, too, is a form of self-authorisation.

### **Agreement between COPFS and the STG**

An agreement was developed by the Crown Office and Procurator Fiscal Service (COPFS) and the Scottish Transplant Group in 2004 (updated in 2008) to cover the potential involvement of the Procurator Fiscal (PF) in organ donation. The most important points are:

- Where there is reason to believe that a death may be reported to the PF, no parts of a body will be removed without the Fiscal's prior consent (section 5 of the Human Tissue (Scotland) Act 2006) of this document).
- The PF may object to removal of organs in a case which is likely to result in a charge of homicide or where, in the time available, insufficient enquiry is able to be carried out to allow an informed decision. There are however procedures available which will allow the PF not to object to transplantation of organs in cases of homicide, but early discussion with the PF is essential;
- The PF will normally permit removal of organs, subject to the need to ensure

that sufficient evidence is available for any subsequent criminal proceedings or Fatal Accident Inquiry and the need to establish that the death has not been caused, or contributed to, by the retrieval operation.

This agreement provides that, where necessary, deaths will be reported to the Procurator Fiscal and, in the case of a potential Category III DCD, the Procurator Fiscal will be advised in advance of cardio-respiratory arrest to enable the Procurator Fiscal to make a rapid and informed decision about donation.

With Government approval, a pilot Category II DCD programme has been developed and will run in Lothian from January 2013, with the initial intention of enabling organ donation from the Emergency Department (ED) at the Royal Infirmary of Edinburgh (RIE). The pilot has the support of the Scottish Fatalities Investigation Unit (SFIU) and forensic pathology in the Royal Infirmary of Edinburgh. A form has been devised that will be sent from the ED at the RIE to the Edinburgh office of the SFIU containing the information needed to allow the Fiscal to decide whether consent can be given to organ donation in each case.

## Terms of Agreement

### General

In any case of proposed donation after circulatory death, once a decision to withdraw life-sustaining treatment has been reached, the Procurator Fiscal should be consulted in advance of proposed treatment withdrawal, if there is reason to believe that the death would need to be reported to the Procurator Fiscal (see Annex 1, which gives details of which deaths, or prospective deaths, **must** be reported to the Procurator Fiscal). Similarly, if the death of a Brain Stem Dead donor needs to be reported to the PF, the death must be reported before any organ donation can take place.

### DBD

It is not essential that the cornea, tendons, heart valves or skin be removed immediately upon death and no special procedure is necessary in this case.

- Organs must be removed very soon after death if they are to be viable. Medical authorities must inform the Procurator Fiscal of any proposed retrieval procedure in appropriate cases as soon as possible after death is confirmed, seeking a decision at the earliest possible moment.

Where there is doubt about the appropriate Procurator Fiscal, the initial contact will be with the District Procurator Fiscal for the District in which the hospital is situated. Contact numbers and an organisational chart are given in Annex 2. The Procurator Fiscal will then either:

decide whether the retrieval should proceed; or make enquiry to establish who is the appropriate Procurator Fiscal to consider the retrieval request.

Procurators Fiscal will immediately instruct any necessary enquiry by the police into the circumstances, so that they may decide whether to consent to the retrieval when death occurs.

Where no objection is made to organ retrieval, it is the responsibility of the Procurator Fiscal to ensure that sufficient evidence is available for any subsequent criminal proceedings or Fatal Accident Inquiry.

It will be necessary to take steps to ensure it can be established that the death has not been caused, or contributed to, by the retrieval procedure.

If there is uncertainty as to whether the retrieval operation could affect evidence, the Procurator Fiscal shall ask the Specialist Nurse for Organ Donation (SN-OD) to put him or her in touch with the senior transplant surgeon on the organ retrieval team to discuss the operation plans and co-operate with any requirement for pathological investigation.

If it is felt that discussions should be assisted by involving a pathologist, the on-call forensic pathologist should be contacted and may attend the retrieval if required.

The following procedure should be adopted in hospitals:

- The retrieval operation will not begin until the death of the potential donor has been established by two senior doctors independent of the transplant team.
- These doctors will, if required, give evidence to that effect, to provide proof that the death of the donor was not caused by the retrieval operation.
- The retrieval surgeon will detail the operative procedure, and any other findings in the patient's medical records, which will be available for the autopsy pathologist should they wish to see them. The retrieval surgeon will also be available for court purposes, if required.

The above procedure ensures that if the Procurator Fiscal then decides that a post-mortem examination is necessary, evidence will be available to prove that the retrieval operation did not contribute to the death of the donor.

## **DCD**

Anyone dying in hospital is a potential DCD organ or tissue donor unless they have a medical contraindication or there is no authorisation for donation. The Fiscal's consent for DCD organ donation is required **before** death occurs. This does not apply in the case of tissue donation, as tissue can be retrieved up until 24 hours (exceptionally 48 hours) after death.

### Category II DCD

The following information is taken from the policy document underpinning the pilot programme in NHS Lothian, with the intention that it should be adopted in other parts of Scotland in due course. The fundamental principles underlying the pilot are:

- It relates only to those aged between 16 and 70 who have a witnessed cardiac arrest, for whom all attempts at resuscitation prove unsuccessful and for whom it is subsequently found that authorisation for organ donation exists;
- There is complete separation of the resuscitation process from any consideration of organ donation;
- The donation pathway is triggered only after referral is made by Emergency Department staff and the Fiscal gives consent in terms of section 5 of the HT(S) 2006 Act; and,
- The surgical team will attend the donor only after death is pronounced by the ED consultant in charge.

Should organ donation not prove possible, existing arrangements for tissue donation in the Emergency Department at the RIE will go ahead in appropriate circumstances.

There may be cases where resuscitation is successful initially, and the patient is transferred to an Intensive Care Unit (ICU). Should treatment in the ICU subsequently prove futile, the patient might then go on to become a Category III DCD donor, in which case the arrangements below will apply.

The following is the procedure adopted in hospitals:

- The retrieval procedure will not be commenced until the death of the potential donor has been established by medical staff independent of the transplant team;
- The medical staff will, if required, give evidence to prove that the death of the donor was not caused by the retrieval operation; and
- The retrieval surgeon will detail the operative procedure, and any other findings in the patient's medical records, which will be available for the pathologist in the event of a post-mortem examination, should the pathologist wish to see them. The retrieval surgeon will also be available for court purposes, if required.

The above procedures ensure that if the Procurator Fiscal then decides to request a post mortem; evidence will be available to prove that the retrieval operation did not contribute to the death of the potential donor.

### Category III DCD

In the majority of these cases, patients will have been admitted to an Intensive Care Unit (ICU) and given full life support. After hours or days of care, it may become clear that further treatment is futile and therefore not in the patient's best interests. With the agreement of the family, a decision may then be taken to withdraw all life-sustaining treatment. Once life-sustaining treatment has been withdrawn, cardio-respiratory arrest will occur after an interval, following which death can be pronounced. The Specialist Nurse-Organ Donation (SNOD) will have checked whether the person had put his or her name on the NHS Organ Donor Register, or otherwise given self-authorisation during his or her lifetime for the donation of organs or tissue after death. If such self-authorisation does not exist, there can be discussion with the nearest relative to obtain authorisation for donation. The circumstances will have been discussed with the Procurator Fiscal in appropriate cases. The retrieval team will have been alerted and will be present to preserve or remove organs or tissue.

It is for Emergency Medicine or Critical Care teams to identify all potential patients for DCD donation and contact the SN-OD. Guidance on legal issues relevant to DCD, as set out in CMO Letters (2010)11 and (2012)08 should be followed.

- The SN-OD will confirm that there are no medical contraindications to donation. This will assist the decision as to whether the death should be reported to the Procurator Fiscal in advance;
- Because of the need to commence organ preservation or donation immediately after death in the case of DCD, it is essential to discuss the circumstances with the Procurator Fiscal in advance whenever the death has to be reported to the Procurator Fiscal. It is also good practice to do this in the case of tissue donation. In general, a Procurator Fiscal, after suitable enquiry, will be able to give a view as to whether or not consent will be given to organ retrieval after death, assuming there is no change in relevant circumstances. Medical authorities must inform the Procurator

Fiscal of any proposed retrieval operation in appropriate cases as soon as possible. Where there is doubt about the appropriate Procurator Fiscal, the initial contact will be with the District Procurator Fiscal for the District in which the hospital is situated. Contact numbers and an organisational chart are given in Annex 2. That Procurator Fiscal will then either:

- decide whether the retrieval should proceed; or
  - make enquiry to establish who is the appropriate Procurator Fiscal to consider the retrieval request.
- 
- Thereafter, the case will proceed to donation if consent is given by the Fiscal in terms of section 5 of the Human Tissue (Scotland) Act 2006.

## **Annex 1**

### **REPORT TO PROCURATOR FISCAL**

#### Annex 1

The following deaths must be reported to the Procurator Fiscal ('reportable deaths'):

#### Unnatural Cause of death

Any death which cannot be entirely attributed to natural causes (whether the primary cause or a contributing factor) including:

- Suspicious deaths – i.e. where homicide cannot be ruled out
- Drug related deaths (including deaths due to adverse drug reactions reportable under the Medicines and Healthcare Products Regulatory Agency (MHRA) (Yellow Card Scheme)
- Accidental deaths (including those resulting from falls)
- Deaths resulting from an accident in the course of employment
- Deaths of children from overlaying or suffocation
- Deaths where the circumstances indicate the possibility of suicide

#### Natural cause of death

Deaths which may be due in whole or part to natural causes but occur in the following circumstances:

- (a) Any death due to natural causes where the cause of death cannot be identified by a medical practitioner to the best of his or her knowledge and belief
- (b) Deaths as a result of neglect/fault

#### Any death:

- which may be related to a suggestion of neglect (including self-neglect) or exposure
- where there is an allegation or possibility of fault on the part of another person, body or organisation

- (c) Deaths of children

#### Any death of a child:

- which is a sudden, unexpected and unexplained perinatal death
- where the body of a newborn is found
- where the death may be categorised as a Sudden Unexpected Death in Infancy ('SUDI')
- which arises following a concealed pregnancy

Any death of a child or young person under the age of eighteen years who is 'looked after' by a local authority, including:

- a child whose name is on the Child Protection Register

- a child who is subject to a supervision requirement made by a Children's Hearing
- a child who is subject to an order, authorisation or warrant made by a Court or Children's Hearing (e.g. a child being accommodated by a local authority in foster care, kinship care, residential accommodation or secure accommodation)
- a child who is otherwise being accommodated by a local authority

(d) Deaths from Notifiable Industrial/Infectious Diseases

Any death:

- due to a Notifiable Industrial Disease or disease acquired as a consequence of the deceased's occupation in terms of column 1 of Part 1 of Schedule 3 to the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (see <http://www.legislation.gov.uk/ukxi/1995/3163/schedule/3/made>)
- which poses an acute and serious risk to public health due to either a Notifiable Infectious Disease or Organism in terms of Schedule 1 of the Public Health (Scotland) Act 2008 (see <http://www.legislation.gov.uk/asp/2008/5/schedule/1>) or any other infectious disease or syndrome,

(e) Deaths under medical or dental care

Any death:

- the circumstances of which are the subject of concern to, or complaint by, the nearest relatives of the deceased about the medical treatment given to the deceased with a suggestion that the medical treatment may have contributed to the death of the patient.
- the circumstances of which might indicate fault or neglect on the part of medical staff or where medical staff have concerns regarding the circumstances of death
- the circumstances of which indicate that the failure of a piece of equipment may have caused or contributed to the death
- the circumstances of which are likely to be subject to an Adverse Event Review (as defined by Healthcare Improvement Scotland)
- where, at any time, a death certificate has been issued and a complaint is later received by a doctor or by the Health Board, which suggests that an act or omission by medical staff caused or contributed to the death
- caused by the withdrawal of life sustaining treatment or other medical treatment to a patient in a permanent vegetative state (whether with or without the authority of the Court of Session).
- which occurs in circumstances raising issues of public safety.

(f) Any death not falling into any of the foregoing categories where the circumstances surrounding the death may cause public anxiety.

## Deaths in legal custody

Any death of a person subject to legal custody. This includes (but is not restricted to) all persons:

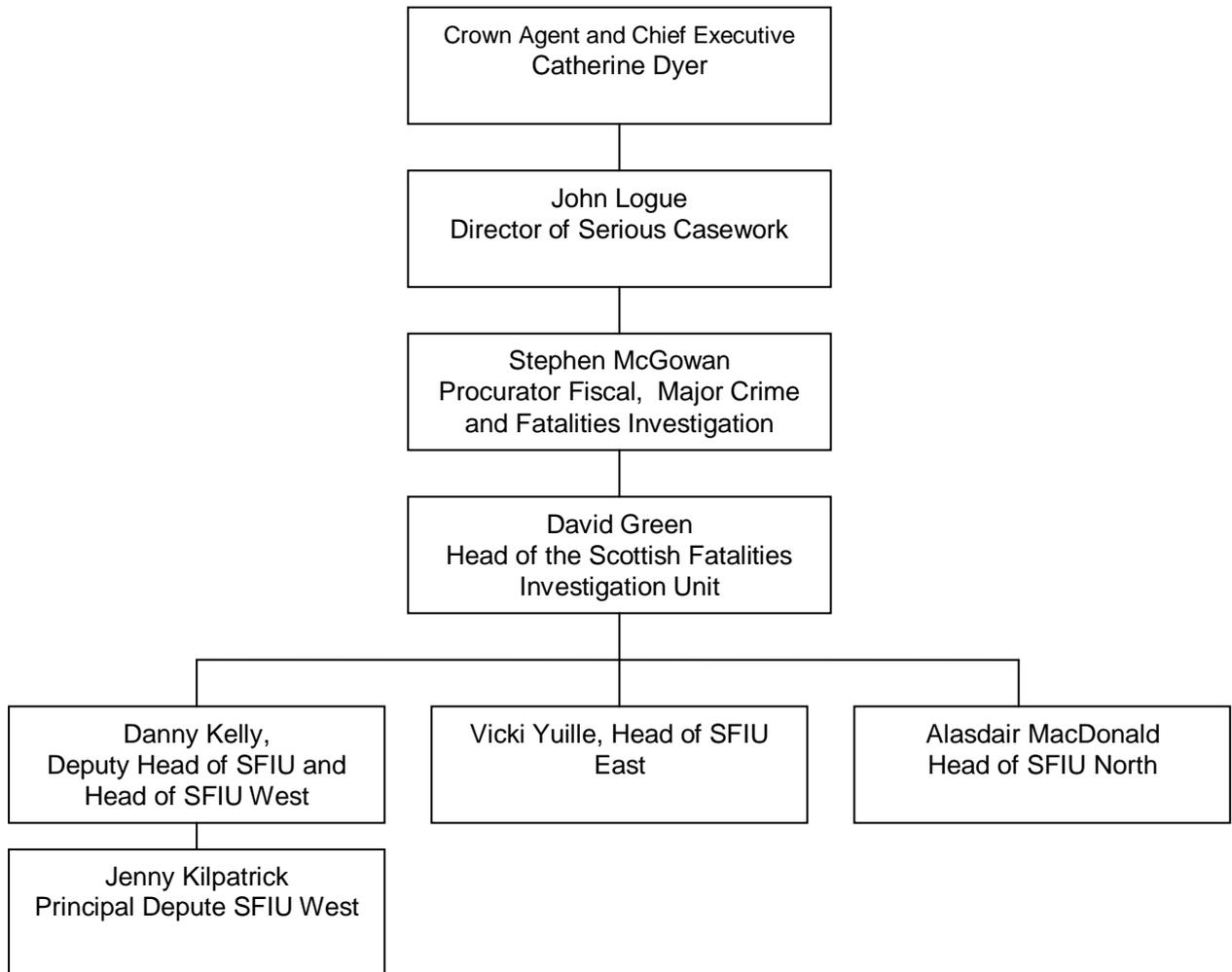
- detained in prison
- arrested or detained in police offices
- in the course of transportation to and from prisons, police offices or otherwise beyond custodial premises e.g. a prisoner who has been admitted to hospital or a prisoner on home leave

## Annex 2

### Procurator Fiscal Contact Numbers

Telephone: 0844 561 3000 from landlines / Telephone: 01389 739 557 from mobiles

### Fiscal Organisational Chart



## **References**

**1. Organs for Transplants: A report from the Organ Donation Taskforce**

[www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_082122](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_082122)

**2. Scottish Government Health Directorate Guidance on Legal Issues Relevant to Donation Following Cardiac Death (CMO Letters (2010)11)**

[www.sehd.scot.nhs.uk/cmo/CMO\(2010\)11.pdf](http://www.sehd.scot.nhs.uk/cmo/CMO(2010)11.pdf)

**3. Scottish Government Health Directorate Guidance on Legal Issues Relevant to Donation Following Cardiac Death (CMO Letter (2012)08)**

[www.sehd.scot.nhs.uk/cmo/CMO\(2012\)08.pdf](http://www.sehd.scot.nhs.uk/cmo/CMO(2012)08.pdf)

**4. A Code of Practice for the diagnosis and confirmation of death. Academy of the Royal Medical Colleges.**

[www.aomrc.org.uk/item/a-code-of-practice-for-the-diagnosis-and-confirmation-of-death.html](http://www.aomrc.org.uk/item/a-code-of-practice-for-the-diagnosis-and-confirmation-of-death.html)

**5. Human Tissue (Scotland) Act 2006.**

[www.legislation.gov.uk/asp/2006/4/contents](http://www.legislation.gov.uk/asp/2006/4/contents)

**6. The Adults with Incapacity (Scotland) Act 2000**

[\\_www.legislation.gov.uk/asp/2000/4/contents](http://www.legislation.gov.uk/asp/2000/4/contents)

**7. The Human Tissue (Scotland) Act 2006 – A Guide to it's implications for NHSScotland**

[www.sehd.scot.nhs.uk/mels/HDL2006\\_46.pdf](http://www.sehd.scot.nhs.uk/mels/HDL2006_46.pdf)

**8. Organ Donation after Circulatory Death: Report of Consensus Conference 2010** British Transplant Society, Department of Health, NHS Blood and Transplant, Intensive Care Society

[www.ics.ac.uk/professional/standards\\_safety\\_quality/standards.../dcd](http://www.ics.ac.uk/professional/standards_safety_quality/standards.../dcd)

## **Useful Links**

### **9. An Ethical Framework for Controlled Donation after Circulatory Death: UK Donation Ethics Committee**

[www.aomrc.org.uk/publications/.../doc\\_view/9322-an-ethical-framework-for-controlled-donation-after-circulatory-death.html](http://www.aomrc.org.uk/publications/.../doc_view/9322-an-ethical-framework-for-controlled-donation-after-circulatory-death.html)

### **10. Taking Organ Transplantation to 2020 - a UK strategy for organ donation and transplantation**

<http://www.nhsbt.nhs.uk/to2020/>

### **11. A Donation and Transplantation Plan for Scotland 2013-2020 – a Scotland specific plan to accompany the UK strategy**

<http://www.scotland.gov.uk/Publications/2013/07/7461>

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Riaghaltas na h-Alba

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