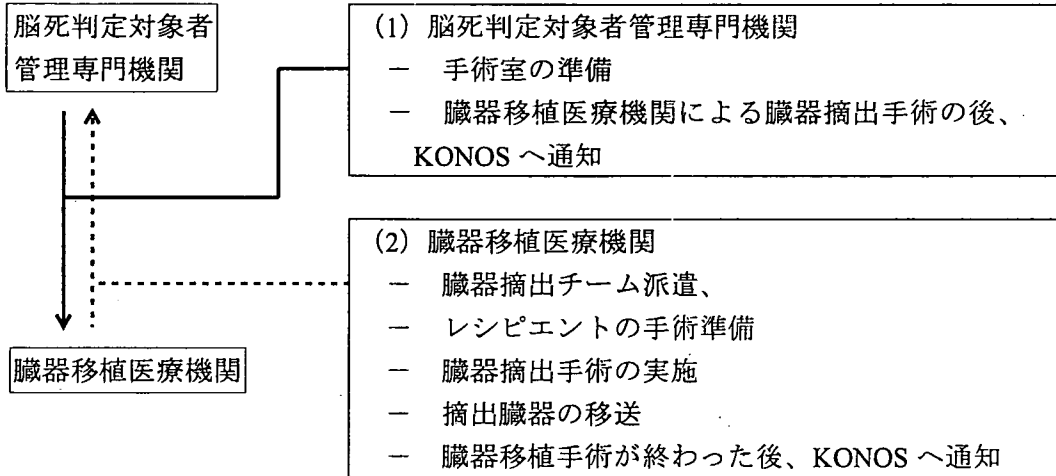


5 臓器摘出および臓器移植



この脳死臓器移植のフローチャートIIは、保健福祉部＝国立臓器移植管理センター『臓器移植管理業務案内』（2004年4月）187頁以下の「脳死臓器移植のフローチャート」に若干手を入れたところはあるが、ほぼそのまま翻訳したものである。

4. 英米における移植をめぐる法律の現状

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分担研究報告書

英米における移植をめぐる法律の現状

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研究要旨

わが国の臓器移植法改正の議論の参考となるであろう、英米における移植をめぐる法律の現状と、近年における議論を紹介する。イギリスにおいては、これまでのオプト・アウトに近いしくみが一転してオプト・イン原理を取る制定法が作られた。一方アメリカは、提供意思を表示できる主体を拡大し、さらに、本人の提供意思があった場合には遺族がこれを覆すことができないことが明文を持って規定された。

A. 研究目的

わが国においては、臓器移植法の制定からほぼ10年が経過し、3年を目途とする見直し期間はとうに過ぎている。この間、提供先の指定（親族への優先提供は認められるか）、現行法下では不可能な小児の移植、いわゆる特別に狭い同意方式をとることの是非、腎臓提供に際しての金銭などの授受や病気腎の移植など、さまざまな事件および議論がおこなわれ、臓器移植法の改正案も国会に提出されている。

本報告では、わが国における議論の参考として、イギリスおよびアメリカにおける近時の議論を紹介する。

B. 研究方法

制定法や議会議事録、および公開されている報告書などを検討した。

（倫理面への配慮）

情報源は基本的に刊行物やウェブサイト上の公知の情報であり、保護を要する秘密情報は扱わない。また、人の身体・精神に直接関係する情報も扱わない。

C. 研究結果

1. イギリスの法状況

（1）これまでのしくみ

イギリスにおける移植に関連する制定法は、Corneal Grafting Act 1952まで遡る。この後、角膜以外の臓器（腎臓）を対象としたHuman Tissue Act 1961（もともと移植だけに限られるわけではなく、教育およ

び研究目的の死体（あるいはその一部）の利用を認めるもので、アメリカ合衆国における統一死体提供法と同じような枠組みである）が制定された（1952年法は同法によって廃止されたが、その後 Corneal Tissue Act 1986 によって医師によらない角膜の摘出が認められている）。

これら制定法は死体由来の臓器・組織の移植のみをカバーするものであり、生体移植については制定法による規制はなかった。ここでは、本人の同意（判断能力のない場合には best interest テスト）が摘出を支える原理であった。そのため、トルコから金銭の支払を受けたドナーが連れてこられ腎臓を提供するという事件がおり、社会問題となった。国会は Human Organ Transplants Act 1989 という制定法を作り、この問題に対応した。同法の下では、非血縁者間の生体移植に限って、ULTRA (Unrelated Live Transplant Regulatory Authority) という政府機関が、金銭の授受がないことを確認した上で承認をしない限り、違法とされることとなった。血縁者間の生体移植についてはこのような承認は不要であり、あいかわらず同意原則によって行なわれ続けた。

(2) そこにおける同意のあり方

イギリス法においては、死体には財産権 (property) は存しない (Handyside's Case (1749) 2 East P. C. 652) から、遺言により自己の死体の処分方法を指示しても当該指示は法的効力を持たないとされてきた (Williams v Williams (1882) 20 Ch D 659)。このため、制定法上も、死後に自分の死体が医学研究目的で解剖されたいとい

う本人の意思は要請 (request) と扱われ (Anatomy Act 1882)、現実に解剖を認可 (authorize) するのは、死者と血縁関係のない死体の管理者 (person lawfully in possession of his body) であった。この考え方は臓器移植法にも受け継がれ、臓器摘出のためには、本人の要請があった場合であっても死体の管理者による認許が必要であったし、本人の要請がない場合であっても、本人および遺族の反対が確認できない場合には、死体の管理者は臓器摘出の認許ができることになっていた。

(3) 近時のスキャンダル

よって、臓器の摘出、保存および研究目的での利用に、本人の積極的な同意が不要であることはもちろんのこと、本人および遺族の反対についても、調査の上反対が知られさえしなければ、これら利用等ができるというのが法律の規定であった。しかし現実には、解剖の際に（不十分ながら）摘出および保存の説明がなされ、同意が取られていたようであった。

問題は、小児心臓血管外科手術の質が問題となった、ブリストル王立病院の事件がきっかけとなって起こった。この調査の際、親の正確な理解と同意なく心臓が保存されていることが発覚し、このような保存は同病院以外にもなされていることが判明した。こどもの心臓であったということもあり、この「無断」保存は大きな社会的スキャンダルとなることとなった。

(4) 新法

NHS法による正式な審問、および国民的な議論を経て、イギリスは、これまでの

法原理を一転させ、同意 (consent) を中核に据える、新たな制定法を作成した。

それによると、本法の対象となる活動は、死体からの「相当な物質」(relevant material) の摘出、その保存と利用、および生体由来の「相当な物質」の保存と利用、である(生体からの摘出は規定されておらず、これまで通りコモンローによる。ただし、後述するように移植目的での生体からの臓器・組織の摘出は33条によって規制される)。ここで「相当な物質」とは、人細胞から構成され、あるいは人細胞を含むものをいう(53条(1))。ただし、配偶子および体外にある胚、生体由来の髪および爪、細胞株のように体外で作成された物質は除かれる。同条(2)、54条(7))。

その上で、本法は、本法の対象となる死体および相当な物質について、後述する別表に定められた目的のほか、本人の診断あるいは治療、礼意のある処分、あるいは国務大臣が規則で定める目的(本法はこれらを称して「適格な目的」(qualifying purpose) という)の範囲内でのみ活動を認め(別表1参照)、これ以外の活動を犯罪とする(8条(1))。ただし、手術や検査、研究利用の過程で出た余剰組織(surplus tissue)は廃棄物(waste)として扱われることができる(44条)。

原則として、別表に定められた目的のための活動に際しては、「適切な同意」(appropriate consent)が必要となる。

別表1の第1部は、解剖学的検査、死因の確定、薬剤や治療の効果を死後に調べること、他者(将来の人を含む)に関係するかもしれない科学的あるいは医学的情報の収集、公衆展示、人体の障害あるいは機能

に関連する研究、移植、であり、第2部は、臨床オーディット(医療が質を保って行われているかを監査すること)、人の健康に関する教育あるいはトレーニング、性能(performance)評価(診断機器の精度管理)、公衆衛生モニタリング、医療の質の確保(quality assurance)である。

死体および死体由来の相当な物質については別表1全部(第1部および第2部)について、生体由来の相当な物質については別表1の第1部のみについて、適切な同意が必要とされる。同意を得ずに活動し、あるいは同意が得られていないのに得られていると虚偽の説明をすると犯罪となる(5条(1)・(2))。ただし、既存試料については、同意要件は必要とされない(9条)。

このように、生体由来の物質の保存と利用については、別表目的のうちの一部について(しかし移植はここに入る)、その利用および保存につき(摘出は前述のように本法によっては規制されない)本人の同意が必要となる。ただし、子ども(18歳未満)については、親責任を有する者も同意することができる。一方、死体からの物質の摘出および死体由来の物質の保存と利用については、本人の生前の同意か、あるいは本人と一定の関係を有していた者の同意で足りる。若干詳述すると、成人については、本人が指名した者か「適格な関係」(qualifying relationship)を有していた者、子どもについては、親責任を有していた者か適格な関係を有していた者が同意をすることができる。適格な関係とは、配偶者またはパートナー、親または子、兄弟または姉妹、祖父母または孫、兄弟姉妹の子、継父または継母、片親を同じくする兄弟また

は姉妹、長い友人、で、この順で序列が認められる (27条(4))。

本法はまた、本法の対象となる活動が適切に行われることを確保するために、さらには一般公衆および研究者に情報およびアドバイスを提供し、政府当局にアドバイスをするために、人組織当局と称する新たな行政機関を設立した。HTAはこの一般的機能の他に、免許の発出、実務要綱 (Codes of Practice) の作成をすることになっている。

HTAの委員は、国務大臣によって指名される他、ウェールズ国民議会 (National Assembly for Wales) および相当な北アイルランド当局もそれぞれ1名ずつ委員を指名することができる。

また、次の三群の行為を行うためにはHTAによる免許が必要となる。

一群は解剖および物質の採取行為である。すなわち、a 解剖学的検査、b 死後検査、c 別表の目的で死体から物質を摘出すること (移植用を除く)。二群は保存行為である。すなわち、d 解剖学的試料の保存、e(i)死体あるいは e(ii)身体由来の相当な物質の保存。そして三群は展示行為、f 死体あるいは死体由来の相当な物質の公衆展示目的での利用。

ただし、国務大臣は、上述の e(ii)に関し、別表の目的のための利用を意図して相当な物質を保存する場合に免許の規定が適用にならない条件を定めることができるものとされ (16条(3))、また、死後100年以上経ったものについては免許の規定は適用にならない (同条(4))。

HTAは、その一般的機能として、本法の第1部および第2部によって課せられる要件、また自らが発する実務要綱 (codes of practice) が遵守されているかを監督するこ

とになっている。また、これを実行あらしめるために、別表5において、HTAによって権限を与えられた者 (duly authorized person) に、査察、立入、搜索押収の権限がみとめられている。

(5) 移植に関する特別規定

①移植目的での商業的取引の禁止 (32条)

移植目的で人物質を商業的に扱うことは犯罪となる。具体的には、報酬を受けて臓器を斡旋することなどが挙げられている。

②生体移植 (33条)

また本法は、移植目的で、生きている人の体から移植可能物質 (transplantable material) を摘出すること、および生体由来の移植可能物質を移植目的で利用することを原則として禁止し、国務大臣の定める規則に従っている場合にのみこれを認めることにしている。この規則により、すべての生体移植はHTAの承認を得ることが必要となっている。

③移植のための処置 (43条)

また、死体が病院、ナーシングホームなど、移植のための利用が可能な施設にある場合、同意が得られないことが確定するまでの間は、施設の管理者は、移植目的で身体部分を保存する (preserve) ための処置を行い、あるいは同目的で死体を持ち続けることが認められた。ただし、処置が、この目的のために必要最小限であり、最も侵襲性が少ないものであることが必要である。

④実務要綱など

前述のように、HTAは法律により実務要綱を策定することが求められている。すでに、Code of Practice 2として、Donation

of organs, tissue and cells for transplantation が策定されているほか、未策定であるが、本法の目的のための死の定義についても実務要綱を策定することが求められている（法 26（2）（d））。

2. アメリカ合衆国の法状況

（1）死体移植

基本的に、死体からの臓器の摘出は、死体の医学研究利用という枠組みで考えられている。とりわけ、1968年に統一州法委員全国会議が各州法のモデル法として Uniform Anatomical Gift Act を示すと、各州はほぼそのままの形で採択し、現在の基本的な法律のスタイルが確立した。それは、成年（多くは 18 歳以上）の本人が生前に、または本人意思（提供意思も反対の意思も）ない場合には遺族が死後に、死体の全部または一部を提供する、というしくみである。

これによるならば、本人の提供の意思表示があった場合には、遺族の反対は法的にはなんら効果を持たないことになるはずである。しかし現実には、本人の提供意思が書面に示されていても、死後に遺族が反対した場合には臓器摘出は行なわれないことが多いようである。これに対応するため、統一州法委員全国会議は 2006 年にこの統一法をリヴァイズし、本人の提供意思は（本人以外の）何人も覆すことをできないことを明文で規定した（8(a））。

また、これまで生前の提供意思を示すこ

とができなかった未成年者について、解放された（emancipated）未成年者などについては本人が提供意思を示すことができるようになったほか、解放されていない未成年者の親および（成年者・未成年者問わず）後見人が、生前に、提供意思を示すことが認められることとなった。

2007 年 1 月現在、同統一法は、11 の州で introduce され、本年中に、さらに 25 の州で introduce される予定だという（<http://www.nccusl.org/Update/DesktopModules/NewsDisplay.aspx?ItemID=174>）。

（2）生体移植

アメリカ合衆国において、生体移植は、基本的には制定法の枠外にある。制定法は概ね、臓器売買を禁ずるのみである（州際取引であれば連邦法である全米臓器移植法の臓器売買禁止規定が適用される（42 U.S.C.A. § 274e））。州内での取引であれば州法が臓器売買を禁止する（例えば、ミシガン州の 333.10204 条）。

D. 研究発表

1. 論文発表
2. 学会発表

E. 知的所有権の取得状況

1. 特許取得
2. 実用新案登録
3. その他

Human Tissue Act 2004

PART 1

REMOVAL, STORAGE AND USE OF HUMAN ORGANS AND OTHER TISSUE FOR SCHEDULED PURPOSES

1 Authorisation of activities for scheduled purposes

(1) The following activities shall be lawful if done with appropriate consent-

(a) the storage of the body of a deceased person for use for a purpose specified in Schedule 1, other than anatomical examination;

(b) the use of the body of a deceased person for a purpose so specified, other than anatomical examination;

(c) the removal from the body of a deceased person, for use for a purpose specified in Schedule 1, of any relevant material of which the body consists or which it contains;

(d) the storage for use for a purpose specified in Part 1 of Schedule 1 of any relevant material which has come from a human body;

(e) the storage for use for a purpose specified in Part 2 of Schedule 1 of any relevant material which has come from the body of a deceased person;

(f) the use for a purpose specified in Part 1 of Schedule 1 of any relevant material which has come from a human body;

(g) the use for a purpose specified in Part 2 of Schedule 1 of any relevant material which has come from the body of a deceased person.

(2) The storage of the body of a deceased person for use for the purpose of anatomical examination shall be lawful if done-

(a) with appropriate consent, and

(b) after the signing of a certificate-

(i) under section 22(1) of the Births and Deaths Registration Act 1953 (c. 20), or

(ii) under Article 25(2) of the Births and Deaths Registration (Northern Ireland) Order 1976 (S.I. 1976/1041 (N.I. 14)),
of the cause of death of the person.

(3) The use of the body of a deceased person for the purpose of anatomical examination shall be lawful if done-

(a) with appropriate consent, and

(b) after the death of the person has been registered-

(i) under section 15 of the Births and Deaths Registration Act 1953, or

(ii) under Article 21 of the Births and Deaths Registration (Northern Ireland) Order 1976.

(4) Subsections (1) to (3) do not apply to an activity of a kind mentioned there if it is done in relation to-

(a) a body to which subsection (5) applies, or

(b) relevant material to which subsection (6) applies.

(5) This subsection applies to a body if-

- (a) it has been imported, or
 - (b) it is the body of a person who died before the day on which this section comes into force and at least one hundred years have elapsed since the date of the person's death.
- (6) This subsection applies to relevant material if
- (a) it has been imported,
 - (b) it has come from a body which has been imported, or
 - (c) it is material which has come from the body of a person who died before the day on which this section comes into force and at least one hundred years have elapsed since the date of the person's death.
- (7) Subsection (1)(d) does not apply to the storage of relevant material for use for the purpose of research in connection with disorders, or the functioning, of the human body if
- (a) the material has come from the body of a living person, and
 - (b) the research falls within subsection (9).
- (8) Subsection (1)(f) does not apply to the use of relevant material for the purpose of research in connection with disorders, or the functioning, of the human body if
- (a) the material has come from the body of a living person, and
 - (b) the research falls within subsection (9).
- (9) Research falls within this subsection if
- (a) it is ethically approved in accordance with regulations made by the Secretary of State, and
 - (b) it is to be, or is, carried out in circumstances such that the person carrying it out is not in possession, and not likely to come into possession, of information from which the person from whose body the material has come can be identified.
- (10) The following activities shall be lawful
- (a) the storage for use for a purpose specified in Part 2 of Schedule 1 of any relevant material which has come from the body of a living person;
 - (b) the use for such a purpose of any relevant material which has come from the body of a living person;
 - (c) an activity in relation to which subsection (4), (7) or (8) has effect.
- (11) The Secretary of State may by order
- (a) vary or omit any of the purposes specified in Part 1 or 2 of Schedule 1, or
 - (b) add to the purposes specified in Part 1 or 2 of that Schedule.
- (12) Nothing in this section applies to
- (a) the use of relevant material in connection with a device to which Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices applies, where the use falls within the Directive, or
 - (b) the storage of relevant material for use falling within paragraph (a).
- (13) In this section, the references to a body or material which has been imported do not include a body or material which has been imported after having been exported with a view to its subsequently being re-imported.

2 "Appropriate consent": children

(1) This section makes provision for the interpretation of "appropriate consent" in section 1 in relation to an activity involving the body, or material from the body, of a person who is a child or has died a child ("the child concerned").

(2) Subject to subsection (3), where the child concerned is alive, "appropriate consent" means his consent.

(3) Where-

(a) the child concerned is alive,

(b) neither a decision of his to consent to the activity, nor a decision of his not to consent to it, is in force, and

(c) either he is not competent to deal with the issue of consent in relation to the activity or, though he is competent to deal with that issue, he fails to do so, "appropriate consent" means the consent of a person who has parental responsibility for him.

(4) Where the child concerned has died and the activity is one to which subsection (5) applies, "appropriate consent" means his consent in writing.

(5) This subsection applies to an activity involving storage for use, or use, for the purpose of-

(a) public display, or

(b) where the subject-matter of the activity is not excepted material, anatomical examination.

(6) Consent in writing for the purposes of subsection (4) is only valid if-

(a) it is signed by the child concerned in the presence of at least one witness who attests the signature, or

(b) it is signed at the direction of the child concerned, in his presence and in the presence of at least one witness who attests the signature.

(7) Where the child concerned has died and the activity is not one to which subsection (5) applies, "appropriate consent" means-

(a) if a decision of his to consent to the activity, or a decision of his not to consent to it, was in force immediately before he died, his consent;

(b) if paragraph (a) does not apply-

(i) the consent of a person who had parental responsibility for him immediately before he died, or

(ii) where no person had parental responsibility for him immediately before he died, the consent of a person who stood in a qualifying relationship to him at that time.

3 "Appropriate consent": adults

(1) This section makes provision for the interpretation of "appropriate consent" in section 1 in relation to an activity involving the body, or material from the body, of a person who is an adult or has died an adult ("the person concerned").

- (2) Where the person concerned is alive, "appropriate consent" means his consent.
- (3) Where the person concerned has died and the activity is one to which subsection (4) applies, "appropriate consent" means his consent in writing.
- (4) This subsection applies to an activity involving storage for use, or use, for the purpose of
- (a) public display, or
 - (b) where the subject-matter of the activity is not excepted material, anatomical examination.
- (5) Consent in writing for the purposes of subsection (3) is only valid if
- (a) it is signed by the person concerned in the presence of at least one witness who attests the signature,
 - (b) it is signed at the direction of the person concerned, in his presence and in the presence of at least one witness who attests the signature, or
 - (c) it is contained in a will of the person concerned made in accordance with the requirements of
 - (i) section 9 of the Wills Act 1837 (c. 26), or
 - (ii) Article 5 of the Wills and Administration Proceedings (Northern Ireland) Order 1994 (S.I. 1994/1899 (N.I. 13)).
- (6) Where the person concerned has died and the activity is not one to which subsection (4) applies, "appropriate consent" means
- (a) if a decision of his to consent to the activity, or a decision of his not to consent to it, was in force immediately before he died, his consent;
 - (b) if
 - (i) paragraph (a) does not apply, and
 - (ii) he has appointed a person or persons under section 4 to deal after his death with the issue of consent in relation to the activity, consent given under the appointment;
 - (c) if neither paragraph (a) nor paragraph (b) applies, the consent of a person who stood in a qualifying relationship to him immediately before he died.
- (7) Where the person concerned has appointed a person or persons under section 4 to deal after his death with the issue of consent in relation to the activity, the appointment shall be disregarded for the purposes of subsection (6) if no one is able to give consent under it.
- (8) If it is not reasonably practicable to communicate with a person appointed under section 4 within the time available if consent in relation to the activity is to be acted on, he shall be treated for the purposes of subsection (7) as not able to give consent under the appointment in relation to it.

4 Nominated representatives

- (1) An adult may appoint one or more persons to represent him after his death in relation to consent for the purposes of section 1.

- (2) An appointment under this section may be general or limited to consent in relation to such one or more activities as may be specified in the appointment.
- (3) An appointment under this section may be made orally or in writing.
- (4) An oral appointment under this section is only valid if made in the presence of at least two witnesses present at the same time.
- (5) A written appointment under this section is only valid if
- (a) it is signed by the person making it in the presence of at least one witness who attests the signature,
 - (b) it is signed at the direction of the person making it, in his presence and in the presence of at least one witness who attests the signature, or
 - (c) it is contained in a will of the person making it, being a will which is made in accordance with the requirements of
 - (i) section 9 of the Wills Act 1837 (c. 26), or
 - (ii) Article 5 of the Wills and Administration Proceedings (Northern Ireland) Order 1994 (S.I. 1994/1899 (N.I. 13)).
- (6) Where a person appoints two or more persons under this section in relation to the same activity, they shall be regarded as appointed to act jointly and severally unless the appointment provides that they are appointed to act jointly.
- (7) An appointment under this section may be revoked at any time.
- (8) Subsections (3) to (5) apply to the revocation of an appointment under this section as they apply to the making of such an appointment.
- (9) A person appointed under this section may at any time renounce his appointment.
- (10) A person may not act under an appointment under this section if
- (a) he is not an adult, or
 - (b) he is of a description prescribed for the purposes of this provision by regulations made by the Secretary of State.

5 Prohibition of activities without consent etc.

- (1) A person commits an offence if, without appropriate consent, he does an activity to which subsection (1), (2) or (3) of section 1 applies, unless he reasonably believes
- (a) that he does the activity with appropriate consent, or
 - (b) that what he does is not an activity to which the subsection applies.
- (2) A person commits an offence if
- (a) he falsely represents to a person whom he knows or believes is going to, or may, do an activity to which subsection (1), (2) or (3) of section 1 applies
 - (i) that there is appropriate consent to the doing of the activity, or
 - (ii) that the activity is not one to which the subsection applies, and
 - (b) he knows that the representation is false or does not believe it to be true.
- (3) Subject to subsection (4), a person commits an offence if, when he does an activity to which section 1(2) applies, neither of the following has been signed in relation to the cause of death of the person concerned

(a) a certificate under section 22(1) of the Births and Deaths Registration Act 1953 (c. 20), and

(b) a certificate under Article 25(2) of the Births and Deaths Registration (Northern Ireland) Order 1976 (S.I. 1976/1041 (N.I. 14)).

(4) Subsection (3) does not apply

(a) where the person reasonably believes

(i) that a certificate under either of those provisions has been signed in relation to the cause of death of the person concerned, or

(ii) that what he does is not an activity to which section 1(2) applies, or

(b) where the person comes into lawful possession of the body immediately after death and stores it prior to its removal to a place where anatomical examination is to take place.

(5) Subject to subsection (6), a person commits an offence if, when he does an activity to which section 1(3) applies, the death of the person concerned has not been registered under either of the following provisions

(a) section 15 of the Births and Deaths Registration Act 1953, and

(b) Article 21 of the Births and Deaths Registration (Northern Ireland) Order 1976.

(6) Subsection (5) does not apply where the person reasonably believes

(a) that the death of the person concerned has been registered under either of those provisions, or

(b) that what he does is not an activity to which section 1(3) applies.

(7) A person guilty of an offence under this section shall be liable

(a) on summary conviction to a fine not exceeding the statutory maximum;

(b) on conviction on indictment

(i) to imprisonment for a term not exceeding 3 years, or

(ii) to a fine, or

(iii) to both.

(8) In this section, "appropriate consent" has the same meaning as in section 1.

6 Activities involving material from adults who lack capacity to consent

Where

(a) an activity of a kind mentioned in section 1(1)(d) or (f) involves material from the body of a person who

(i) is an adult, and

(ii) lacks capacity to consent to the activity, and

(b) neither a decision of his to consent to the activity, nor a decision of his not to consent to it, is in force,

there shall for the purposes of this Part be deemed to be consent of his to the activity if it is done in circumstances of a kind specified by regulations made by the Secretary of State.

7 Powers to dispense with need for consent

(1) If the Authority is satisfied-

- (a) that relevant material has come from the body of a living person,
- (b) that it is not reasonably possible to trace the person from whose body the material has come ("the donor"),
- (c) that it is desirable in the interests of another person (including a future person) that the material be used for the purpose of obtaining scientific or medical information about the donor, and
- (d) that there is no reason to believe
 - (i) that the donor has died,
 - (ii) that a decision of the donor to refuse to consent to the use of the material for that purpose is in force, or
 - (iii) that the donor lacks capacity to consent to the use of the material for that purpose,it may direct that subsection (3) apply to the material for the benefit of the other person.

(2) If the Authority is satisfied-

- (a) that relevant material has come from the body of a living person,
- (b) that it is desirable in the interests of another person (including a future person) that the material be used for the purpose of obtaining scientific or medical information about the person from whose body the material has come ("the donor"),
- (c) that reasonable efforts have been made to get the donor to decide whether to consent to the use of the material for that purpose,
- (d) that there is no reason to believe
 - (i) that the donor has died,
 - (ii) that a decision of the donor to refuse to consent to the use of the material for that purpose is in force, or
 - (iii) that the donor lacks capacity to consent to the use of the material for that purpose, and
- (e) that the donor has been given notice of the application for the exercise of the power conferred by this subsection,
it may direct that subsection (3) apply to the material for the benefit of the other person.

(3) Where material is the subject of a direction under subsection (1) or (2), there shall for the purposes of this Part be deemed to be consent of the donor to the use of the material for the purpose of obtaining scientific or medical information about him which may be relevant to the person for whose benefit the direction is given.

(4) The Secretary of State may by regulations enable the High Court, in such circumstances as the regulations may provide, to make an order deeming there for the purposes of this Part to be appropriate consent to an activity consisting of

- (a) the storage of the body of a deceased person for use for the purpose of research in

connection with disorders, or the functioning, of the human body,

(b) the use of the body of a deceased person for that purpose,

(c) the removal from the body of a deceased person, for use for that purpose, of any relevant material of which the body consists or which it contains,

(d) the storage for use for that purpose of any relevant material which has come from a human body, or

(e) the use for that purpose of any relevant material which has come from a human body.

8 Restriction of activities in relation to donated material

(1) Subject to subsection (2), a person commits an offence if he

(a) uses donated material for a purpose which is not a qualifying purpose, or

(b) stores donated material for use for a purpose which is not a qualifying purpose.

(2) Subsection (1) does not apply where the person reasonably believes that what he uses, or stores, is not donated material.

(3) A person guilty of an offence under this section shall be liable

(a) on summary conviction to a fine not exceeding the statutory maximum;

(b) on conviction on indictment

(i) to imprisonment for a term not exceeding 3 years, or

(ii) to a fine, or

(iii) to both.

(4) In subsection (1), references to a qualifying purpose are to

(a) a purpose specified in Schedule 1,

(b) the purpose of medical diagnosis or treatment,

(c) the purpose of decent disposal, or

(d) a purpose specified in regulations made by the Secretary of State.

(5) In this section, references to donated material are to

(a) the body of a deceased person, or

(b) relevant material which has come from a human body,

which is, or has been, the subject of donation.

(6) For the purposes of subsection (5), a body, or material, is the subject of donation if authority under section 1(1) to (3) exists in relation to it.

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12 Interpretation of Part 1

In this Part, "excepted material" means material which has

(a) come from the body of a living person, or

(b) come from the body of a deceased person otherwise than in the course of use of the body for the purpose of anatomical examination.

PART 2

REGULATION OF ACTIVITIES INVOLVING HUMAN TISSUE

The Human Tissue Authority

13 The Human Tissue Authority

- (1) There shall be a body corporate to be known as the Human Tissue Authority (referred to in this Act as "the Authority").
- (2) Schedule 2 (which makes further provision about the Authority) has effect.

14 Remit

- (1) The following are the activities within the remit of the Authority
 - (a) the removal from a human body, for use for a scheduled purpose, of any relevant material of which the body consists or which it contains;
 - (b) the use, for a scheduled purpose, of
 - (i) the body of a deceased person, or
 - (ii) relevant material which has come from a human body;
 - (c) the storage of an anatomical specimen or former anatomical specimen;
 - (d) the storage (in any case not falling within paragraph (c)) of
 - (i) the body of a deceased person, or
 - (ii) relevant material which has come from a human body,for use for a scheduled purpose;
 - (e) the import or export of
 - (i) the body of a deceased person, or
 - (ii) relevant material which has come from a human body,for use for a scheduled purpose;
 - (f) the disposal of the body of a deceased person which has been
 - (i) imported for use,
 - (ii) stored for use, or
 - (iii) used,for a scheduled purpose;
 - (g) the disposal of relevant material which
 - (i) has been removed from a person's body for the purposes of his medical treatment,
 - (ii) has been removed from the body of a deceased person for the purposes of an anatomical, or post-mortem, examination,
 - (iii) has been removed from a human body (otherwise than as mentioned in sub-paragraph (ii)) for use for a scheduled purpose,
 - (iv) has come from a human body and been imported for use for a scheduled purpose,or
 - (v) has come from the body of a deceased person which has been imported for use for a scheduled purpose.

(2) Without prejudice to the generality of subsection (1)(a) and (b), the activities within the remit of the Authority include, in particular-

- (a) the carrying-out of an anatomical examination, and
- (b) the making of a post-mortem examination.

(3) An activity is excluded from the remit of the Authority if-

- (a) it relates to the body of a person who died before the day on which this section comes into force or to material which has come from the body of such a person, and
- (b) at least one hundred years have elapsed since the date of the person's death.

(4) The Secretary of State may by order amend this section for the purpose of adding to the activities within the remit of the Authority.

(5) In this section, "relevant material", in relation to use for the scheduled purpose of transplantation, does not include blood or anything derived from blood.

15 General functions

The Authority shall have the following general functions-

(a) maintaining a statement of the general principles which it considers should be followed-

- (i) in the carrying-on of activities within its remit, and
- (ii) in the carrying-out of its functions in relation to such activities;

(b) providing in relation to activities within its remit such general oversight and guidance as it considers appropriate;

(c) superintending, in relation to activities within its remit, compliance with-

- (i) requirements imposed by or under Part 1 or this Part, and
- (ii) codes of practice under this Act;

(d) providing to the public, and to persons carrying on activities within its remit, such information and advice as it considers appropriate about the nature and purpose of such activities;

(e) monitoring developments relating to activities within its remit and advising the Secretary of State, the National Assembly for Wales and the relevant Northern Ireland department on issues relating to such developments;

(f) advising the Secretary of State, the National Assembly for Wales or the relevant Northern Ireland department on such other issues relating to activities within its remit as he, the Assembly or the department may require.

Licensing

16 Licence requirement

(1) No person shall do an activity to which this section applies otherwise than under the authority of a licence granted for the purposes of this section.

(2) This section applies to the following activities-

- (a) the carrying-out of an anatomical examination;
- (b) the making of a post-mortem examination;

(c) the removal from the body of a deceased person (otherwise than in the course of an activity mentioned in paragraph (a) or (b)) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation;

(d) the storage of an anatomical specimen;

(e) the storage (in any case not falling within paragraph (d)) of

(i) the body of a deceased person, or

(ii) relevant material which has come from a human body,

for use for a scheduled purpose;

(f) the use, for the purpose of public display, of

(i) the body of a deceased person, or

(ii) relevant material which has come from the body of a deceased person.

(3) The Secretary of State may by regulations specify circumstances in which storage of relevant material by a person who intends to use it for a scheduled purpose is excepted from subsection (2)(e)(ii).

(4) An activity is excluded from subsection (2) if

(a) it relates to the body of a person who died before the day on which this section comes into force or to material which has come from the body of such a person, and

(b) at least one hundred years have elapsed since the date of the person's death.

(5) The Secretary of State may by regulations amend this section for the purpose of

(a) adding to the activities to which this section applies,

(b) removing an activity from the activities to which this section applies, or

(c) altering the description of an activity to which this section applies.

(6) Schedule 3 (which makes provision about licences for the purposes of this section) has effect.

(7) In subsection (2)

(a) references to storage do not include storage which is incidental to transportation, and

(b) "relevant material", in relation to use for the scheduled purpose of transplantation, does not include blood or anything derived from blood.

17 Persons to whom licence applies

The authority conferred by a licence extends to

(a) the designated individual,

(b) any person who is designated as a person to whom the licence applies by a notice given to the Authority by the designated individual, and

(c) any person acting under the direction of

(i) the designated individual, or

(ii) a person designated as mentioned in paragraph (b).

18 Duty of the designated individual

It shall be the duty of the individual designated in a licence as the person under whose supervision the licensed activity is authorised to be carried on to secure-

- (a) that the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity,
- (b) that suitable practices are used in the course of carrying on that activity, and
- (c) that the conditions of the licence are complied with.

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23 Conduct of licensed activities

- (1) Directions may impose requirements in relation to the conduct of the activity which a licence authorises to be carried on.
- (2) Directions under subsection (1) may be given in relation to licences generally, licences of a particular description or a particular licence.
- (3) A person shall comply with a requirement imposed by directions under subsection (1) if it is applicable to him.

24 Changes of licence circumstance

- (1) Directions may make provision for the purpose of dealing with a situation arising in consequence of
 - (a) the variation of a licence, or
 - (b) a licence ceasing to have effect.
- (2) Directions under subsection (1)(a) may impose requirements
 - (a) on the holder of the licence;
 - (b) on a person who is the designated individual immediately before, or immediately after, the variation;
 - (c) on any other person, if he consents.
- (3) Directions under subsection (1)(b) may impose requirements
 - (a) on the person who is the holder of the licence immediately before the licence ceases to have effect;
 - (b) on the person who is the designated individual at that time;
 - (c) on any other person, if he consents.
- (4) Directions under subsection (1) may, in particular, require anything kept, or information held, in pursuance of the licence to be transferred in accordance with the directions.
- (5) Where a licence has ceased to have effect by reason of the death or dissolution of its holder, anything subsequently done by a person before directions are given under subsection (1) shall, if the licence would have been authority for doing it, be treated as authorised by a licence.

25 Breach of licence requirement

- (1) A person who contravenes section 16(1) commits an offence, unless he reasonably believes-
- (a) that what he does is not an activity to which section 16 applies, or
 - (b) that he acts under the authority of a licence.
- (2) A person guilty of an offence under subsection (1) shall be liable-
- (a) on summary conviction to a fine not exceeding the statutory maximum;
 - (b) on conviction on indictment-
 - (i) to imprisonment for a term not exceeding 3 years, or
 - (ii) to a fine, or
 - (iii) to both.

Codes of practice

26 Preparation of codes

- (1) The Authority may prepare and issue codes of practice for the purpose of-
- (a) giving practical guidance to persons carrying on activities within its remit, and
 - (b) laying down the standards expected in relation to the carrying-on of such activities.
- (2) The Authority shall deal under subsection (1) with the following matters-
- (a) the carrying-out of anatomical examinations;
 - (b) the storage of anatomical specimens;
 - (c) the storage and disposal of former anatomical specimens;
 - (d) the definition of death for the purposes of this Act;
 - (e) communication with the family of the deceased in relation to the making of a post-mortem examination;
 - (f) the making of post-mortem examinations;
 - (g) communication with the family of the deceased in relation to the removal from the body of the deceased, for use for a scheduled purpose, of any relevant material of which the body consists or which it contains;
 - (h) the removal from a human body, for use for a scheduled purpose, of any relevant material of which the body consists or which it contains;
 - (i) the storage for use for a scheduled purpose, and the use for such a purpose, of-
 - (i) the body of a deceased person, or
 - (ii) relevant material which has come from a human body;
 - (j) the storage for use for a scheduled purpose, and the use for such a purpose, of an existing holding within the meaning of section 9;
 - (k) the import, and the export, of-
 - (i) the body of a deceased person, or
 - (ii) relevant material which has come from a human body,
 for use for a scheduled purpose;
 - (l) the disposal of relevant material which-
 - (i) has been removed from a human body for use for a scheduled purpose, or