Good Practice Guide on Paternity Testing Services

For organisations that provide genetic paternity testing services direct to the public
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For Recipient’s Use
## Contents

Introduction ........................................................................................................................................... 5

- What is paternity testing? .................................................................................................................. 5
- Why issue guidance relating to paternity testing services? ............................................................... 6
- To whom does the Guide apply? ........................................................................................................ 6
- Why publish new guidance on paternity testing services? .............................................................. 6

Key principles .................................................................................................................................... 7

Application of the Good Practice Guide ........................................................................................... 8

The Good Practice Guide on Paternity Testing Services .............................................................. 9

1. Information to be provided to parties giving consent to a paternity test ...................................... 10

- Advertising ........................................................................................................................................ 11
- Information to individual parties to the test ...................................................................................... 11

2. Validation and Accreditation .......................................................................................................... 12

- Ministry of Justice accreditation where a court has directed a parentage test under section 20 of the Family Law Reform Act 1969 .................................................................................. 14

3. Consent ........................................................................................................................................... 16

- Consent under ordinary medical law principles ................................................................................ 17
- Consent from a child ............................................................................................................................ 17
- Consent from an adult ......................................................................................................................... 19
- Disputed consent ............................................................................................................................... 19
- Consent for the purpose of Section 45 of the Human Tissue Act 2004 – non-consensual analysis of DNA .......................................................................................................................... 20
- The role of the sampler ...................................................................................................................... 22
- Home paternity kits ........................................................................................................................... 23
- ‘Motherless’ testing ............................................................................................................................ 24
- Prenatal paternity testing .................................................................................................................... 25

4. Authentication .................................................................................................................................. 26

- Paternity tests which may be admissible as evidence in court ......................................................... 26
- Tests intended for private uses .......................................................................................................... 27

5. Confidentiality and Storage of Samples of Records ....................................................................... 29

- Confidentiality ................................................................................................................................... 29

- Data Protection Act 1998 ................................................................................................................. 30

- Annex A ............................................................................................................................................. 31
- Annex B ............................................................................................................................................. 32
- Annex C ............................................................................................................................................. 33
Introduction

1. This Good Practice Guide on Paternity Testing Services is a revised version of the UK Health Departments’ Code of Practice and Guidance on Paternity Testing Services, published in March 2001. This Guide applies across the United Kingdom, applying equally in England, Wales and Northern Ireland; where there are legal differences in Scotland, these have been highlighted within the guide.

2. We are grateful for the comments and suggestions we have received from the Devolved Administrations and all of the organisations, Government Departments and providers of genetic paternity testing services in the drafting of this new Guide.

What is paternity testing?

3. Paternity testing involves comparing the DNA (or sometimes blood) of individuals to determine their biological relationship. Most commonly, tests are undertaken to determine whether a man is the biological father of a child or if two or more adults are related. The scientific testing methods used to perform paternity testing have improved dramatically over the past twenty years.

4. Advances in modern genetics in the late 1990s meant that it was possible to produce accurate results from cells taken from inside the mouth using buccal swabs. Such sampling methods were welcomed as they were often less invasive for the individuals involved. Moreover, they made it possible for people to conduct paternity tests without any professional medical involvement by buying an over-the-counter sampling kit, or via the Internet and returning the sample by post to the genetic testing company. In recent years, we have also seen the advent of walk-in DNA centres in the UK, which offer customers paternity tests without a prior appointment.

5. The market for private paternity testing services, available over the counter or via the Internet has expanded considerably in recent years. The majority of the companies offering tests in the UK are reputable bodies who participate in the appropriate accreditation and quality assurance schemes. However, in recent years there have been cases of individuals or companies who have fallen short of the expected standards.

6. Further, although routine paternity testing is carried out with samples taken from the mother, putative father and the child, increasingly tests have been undertaken using samples provided by the child and putative father alone – a practice we refer to in this document as “motherless testing”.
Why issue guidance relating to paternity testing services?

7. By 2001, it was clear that the advent of new technologies which made it possible to conduct paternity tests without the aid of a medical practitioner, also heralded a need for the Government to produce some good-practice guidance in relation to paternity testing, to address the ethical and procedural issues which then arose. The Code of Practice and Guidance on Paternity Testing Services was primarily designed to protect vulnerable children and adults involved in cases of disputed paternity.

8. The Code of Practice was, as this new Good Practice Guide is, non-statutory, meaning that compliance is voluntary. However, in some cases the Guide reflects statutory requirements, setting out clear standards for providers of genetic paternity testing services direct to the public as well as to those who commissioned paternity services such as general medical practitioners and other clinicians whose advice may be sought by members of the public when there is a concern relating to paternity.

9. All Government and public bodies who commission services or use the results of paternity tests as part of their business are expected to, so far as is practicable, ensure that those supplying services comply with this Guide.

To whom does the Guide apply?

10. The Good Practice Guide is aimed at organisations that provide - and advertise that they provide - genetic paternity testing services direct to the public. It will also be of interest to those who commission such services, to general medical practitioners and other clinicians whose advice may be sought by members of the public and organisations with an interest in this area.

11. As part of the Ministry of Justice’s criteria to be added to their list of bodies that may carry out parentage tests where directed by a civil (including family) court in England and Wales, under section 20 of the Family Law Reform Act 1969, organisations are obliged to give an undertaking to comply with the Guide when carrying out “section 20” court-directed paternity tests. However, the Government strongly encourages all providers of paternity testing services to adhere to the Guide for all paternity tests.

Why publish new guidance on paternity testing services?

12. The Government has an interest, through its responsibility for consumer protection, in setting out the framework for protecting the welfare of those subjected to genetic paternity testing, especially children. The Guide sets out the standards to be expected of organisations that seek to deliver genetic paternity services direct to the public.
The Good Practice Guide on Paternity Testing Services

13. It is essential that the Guide reflects new legislation relating to the removal, storage, use and disposal of human bodies, organs and tissue from the living and deceased as set out in the Human Tissue Act 2004 and Human Tissue (Scotland) Act 2006. In particular, the Guide must reflect changes in the law in respect of the DNA theft offence contained in the Human Tissue Acts, which came into effect on 1 September 2006.

Key Principles

14. The Good Practice Guide should be read with the following principles in mind:

- The best interests of the child should be a primary concern of organisations and individuals concerned with facilitating and undertaking genetic paternity tests.

- Paternity tests should not be bought by people under 16 years of age.

- It is necessary to consider whether consent is needed for different parts of the testing process. Consent will be needed for a sample to be taken from the people being tested and for the material to be used or stored for the purpose of obtaining scientific or medical information which may be relevant to another person or otherwise than for an excepted purpose.

- In England and Wales, the first requirement comes from the ordinary principles of law relating to consent.

- The second requirement comes from the Human Tissue Act 2004. These requirements are explained in more detail below.

- It is an offence under section 45 of the Human Tissue Act 2004 to possess bodily material (material from a human body that contains human cells) with the intention of analysing the DNA and using the results otherwise than for an excepted purpose without qualifying consent. If, however, appropriate consent has been obtained under the Human Tissue Act for the purpose of the material being used and/or stored to obtain scientific or medical information from the material which may be relevant to another person then possession will be lawful (see below).

- Samples should only be taken from a child if the sampler – a person who takes a sample on behalf of a supplier, for testing purposes – and the organisation providing the test, are satisfied that those consenting to the taking of a sample from the child are authorised to do so.

- Those consenting to testing must have had an opportunity to consider the possible implications raised by knowledge of the results of the test.
The results of tests undertaken by organisations that do not meet the requirements of the Guide might not be recognised by Government Departments, Government agencies or in any proceedings instituted in a court of law.

The Guide is intended to apply in England, Scotland, Wales and Northern Ireland. The main differences in legislation in Scotland are noted. However, if detailed advice on the provision of paternity testing services in Scotland and Northern Ireland is needed, then the Scottish Executive or the Department of Health and Social Services in Northern Ireland should be contacted. Contact details are available at Annex B.

### Application of the Guide

15. Adherence to the Good Practice Guide on Paternity Testing Services remains voluntary, however, it has been drafted to complement the Human Tissue Act 2004 and the Human Tissue (Scotland) Act 2006, which set out a new legal framework for the removal, storage, use and disposal of human bodies, organs and tissue from the living and deceased.

16. The Human Tissue Act also establishes the Human Tissue Authority (HTA) as the body responsible for regulating these matters. As part of the HTA’s regulatory remit, it issues Codes of Practice and other practical advice about the Human Tissue Act to ensure best practice is adhered to by the sectors it regulates. The HTA also gives advice and information to the Secretary of State for Health and the public about issues in its remit.

17. This Good Practice Guide reflects the Human Tissue Authority Code of Practice on Consent. It also adheres to the Advertising Standards Authority’s Advertising Codes and is relied on as a source of good practice by Government Departments and agencies. Compliance with the Guide is a requirement for bodies on the Ministry of Justice’s list of bodies accredited to carry out a court-directed test under section 20 of the Family Law Reform Act 1969 (see paragraph 11). These Government departments and agencies are responsible for enforcing their statutory or regulatory functions in relation to this Guide.

18. Aspects of the Guide, which are considered essential elements of good practice appear in blue print and are boxed.
GOOD PRACTICE GUIDE ON PATERNITY SERVICES

The UK Health Departments encourage those offering genetic paternity testing services to abide by this Good Practice Guide, the Human Tissue Act 2004 and the Human Tissue (Scotland) Act 2006, and the Human Tissue Authority’s Code of Practice on Consent, thereby enabling the public to access high quality paternity testing services to continue without the need for specific statutory controls.

Section 45 of the Human Tissue Act 2004 does not alter the criminal law on theft. Under the Act it is an offence to possess bodily material (material from a human body that consists of or includes human cells) with the intention of analysing DNA in it without qualifying consent and using it for a purpose which is not excepted.

Under the Human Tissue Act, a person who commits the offence of DNA testing without consent may be liable to a fine, and/or a term of imprisonment of up to three years, or both. Any evidence of criminal activity should be reported to the relevant authorities, such as the police. It is possible that the person who provides the material to a company for processing and the company itself could be committing an offence.

This Guide does not amend or limit any existing law.

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1 The following types of bodily material are excepted (a) 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, (b) existing holdings where the person who has it is not in possession, and not likely to come into possession, of information from which the individual from whose body the material has come can be identified, or (c) embryos outside the human body.

2 A number of purposes are excepted purposes – see Schedule 4 to the Human Tissue Act 2004. Where the DNA in bodily material is to be analysed for the purpose of finding out scientific or medical information which may be relevant to another person and appropriate consent has been obtained for the purpose of section 1(1) of the Act use of the DNA analysis results will be an excepted purpose.
1. Information to be provided to parties giving consent to a paternity test.

Those giving consent to a test should be fully informed of its purpose, accuracy and the potential consequences of the test result.

Anyone carrying out a paternity test should have mechanisms in place to ensure that, before the test is performed, those giving consent for a test are fully informed. They should understand the nature of the test, its purpose, the risks involved in the testing process of the test and the potential consequences of the test result.

They should be informed of the normal degree of accuracy that can be expected from the testing technique employed.

The result of the test should include a clear statement that indicates the accuracy of the test with regard to the type of the samples examined.

All advertising, marketing and customer information material must include a prominent phrase such as:

“It may be a criminal offence under the Human Tissue Act 2004, to have bodily material with the intention to analyse human DNA in the material and use the result for certain purposes without qualifying consent. This offence carries a penalty of up to 3 years imprisonment or a fine or both.”

All advertising, marketing and customer information material must be responsible and not prey on peoples’ fears. It must not actively promote:

- the motherless testing of young children
- prenatal paternity testing
Advertising

1.1 Whilst providers of paternity testing services are not legally prohibited from advertising their products, to abide by this Guide, they must comply with the Advertising Standards Authority’s advertising codes in respect of non-broadcast (non-broadcast advertisements, sales promotions and direct marketing communications) and broadcast (radio and television) advertisements. The Advertising Standards Authority is the independent body set up by the advertising industry to police the rules laid down in the advertising codes. Companies who fail to comply with the advertising codes may be subject to sanctions.

1.2 Bodies accredited by the Ministry of Justice must undertake to limit any statement regarding Ministry of Justice accredited status on any promotional material, advertising, or web-site information to the following:

“[Name of Organisation] has been accredited by the Ministry of Justice as a body that may carry out parentage tests directed by the civil courts in England and Wales under section 20 of the Family Law Reform Act 1969”.

The Ministry of Justice is clear that phrases such as ‘Government approved’, ‘Lord Chancellor approved’ or ‘Ministry of Justice approved’ are misleading and therefore not acceptable.

1.3 Suppliers should also avoid the use of expressions such as “court approved” or “court admissible”, which suggest test results will automatically be admissible as evidence by a court in the future.

1.4 Companies whose advertisements are deemed to aid and abet, counsel or procure the commission of an offence under the Human Tissue Act 2004 or Human Tissue Act (Scotland) 2006 may themselves be committing a criminal offence.

Information to individual parties to the Test

1.5 Suppliers must provide suitable and sufficient information to enable the customer to understand the testing techniques to be employed, the scope and limitations and the use to which the results may be put. For example, where home kits

4 Adverse publicity may result from the rulings published by the Advertising Standards Authority weekly on its website. The media, contractors and service providers may withhold their services or deny access to space. Trading privileges (including direct mail discounts) and recognition may be revoked, withdrawn or temporarily withheld. Pre-vetting may be imposed and, in some cases, non-complying parties can be referred to the Office of Fair Trading for action, where appropriate, under the Control of Misleading Advertisements Regulations.

Advertising Standard Authority decisions are subject to independent review, including in exceptional cases by the Administrative Division of the High Court.
are used, it must be made clear to the customer that the ensuing results may not be admissible as evidence in a court.

1.6 A key principle of this Good Practice Guide is that, where a paternity test is being commissioned to establish the paternity of a child, the best interests of the child should be a primary concern, whether the test is commissioned for legal or private reasons. In order to reinforce this message, we recommend that providers of genetic testing services provide their samplers – people who take a sample, on behalf of a supplier, for testing purposes - with clear user instructions. These instructions should cover: the need to take into account the views of the child where appropriate, the wider welfare concerns of the child and the need to ensure that proper legal measures have been taken to obtain consent.

1.7 Suppliers must ensure that those consenting to a paternity test (including those consenting on behalf of a child) should be aware of the significance and possible irrevocable consequences that knowledge of the results of the test may bring. If customers appear uncertain of the implications of test results for them, suppliers must recommended that they seek independent advice or counselling. Some of the organisations able to provide such help are listed at the back of this document at Annex B.

1.8 It is recommended that suppliers work with appropriate professional and voluntary bodies when developing advertising and customer information materials.

1.9 In line with the Disability Discrimination Act 1995, material must be provided in a suitable format for people with physical or sensory impairments, where appropriate. It is also good practice to provide for those whose first language is not English.
2. Validation and Accreditation.

Organisations offering genetic paternity testing services to the public must use appropriate testing techniques and provide assured levels of accuracy and reliability

All organisations offering parentage testing services must be accredited to ISO/IEC 17025 for the appropriate testing scope by an accreditation body which complies with ISO/IEC 17011 (formerly ISO Guide 58), thereby providing independent confirmation of relevant standards and guides. The accreditation body shall be a full member of the International Laboratory Accreditation Cooperation (ILAC) or a Regional Co-operation body whose mutual recognition arrangement or multi-lateral agreement (MRA or MLA) has been successfully evaluated by ILAC. (The United Kingdom Accreditation Service (UKAS) complies with these conditions.)

Continued registration with such a body will be dependent upon satisfactory audits being performed at regular intervals by the accreditation body to ensure continued compliance with the appropriate standards.

2.1 Compliance with the above standards, and other quality-based standards, ensures that the organisation has put in place a reliable system to validate the whole testing process including the training of laboratory and support staff. The system should encompass the whole process from the provision of information to the public (whether written, oral or electronic), sampling procedures, laboratory techniques, equipment and materials through to the delivery of results. Further, compliance demonstrates the organisation’s ability to consistently provide products which meet customer and applicable regulatory requirements.

Organisations offering genetic testing services are encouraged to:

- Ensure that a senior officer or manager is responsible for verifying staff competence and that, where appropriate, these standards are maintained by continuing training or experience.

- Take part in a recognised external quality assurance scheme, such as that organised by the International Society of Forensic Genetics Organisations.
• Provide those taking samples on their behalf with instructions covering matters such as consent, confidentiality, the authentication of samples, and information to be provided to donors.

• Service providers and manufacturers of testing devices must ensure that reagents and materials used in their testing processes comply with statutory requirements. The 'In Vitro Diagnostic Medical Devices Directive' may apply. Further information on the Directive is available from the Medicines and Healthcare products Regulatory Agency (MHRA) (see Annex B for details).

2.2 To ensure that sampling techniques are universally applied and maintained, it is recommended that, those taking samples use testing kits provided by testing organisations and adhere to agreed protocols covering topics such as the provision of information to the parties to the test as well as the actual taking of the sample.

2.3 Where a public body or its agency commission tests, they will normally provide testing organisations with any particular requirements that they may have. These may cover such matters as the authentication of samples, advice to be provided to the public, requirements around consent for a sample to be taken, disclosure to a third party etc.

Ministry of Justice accreditation where a court has directed a parentage test under section 20 of the Family Law Reform Act 1969.

2.4 The Ministry of Justice maintains a list of organisations, which are accredited to carry out parentage tests where directed by a civil court under section 20 of the Family Law Reform Act 1969. For a body to be eligible to be included on the list, the Ministry of Justice’s current criteria include that:

• Applicants must make a written application on a form provided by the Ministry of Justice, which must be signed and submitted in hard copy.

• They have a current and valid ISO 17025 Certificate that has been issued by an accreditation body, which complies with ISO/IEC 17011 (formerly ISO Guide 58) and is a full member of the International Laboratory Accreditation Cooperation (ILAC). (The United Kingdom Accreditation Service (UKAS) complies with these conditions.) An original certificate of a certified copy must be submitted with the application form.

• They give an undertaking to comply with this Good Practice Guide on Paternity Testing Services, or any revised version thereof.

• The Ministry of Justice will not consider intermediary organisations.

• The Ministry of Justice will conduct an annual review of the continuing eligibility of each body on the list.
2.5 Together with the advertising restrictions set out in paragraph 1.2 of this Guide, and a general undertaking to comply with this good practice, the Ministry of Justice stipulates that bodies wishing to be accredited must undertake to comply, and ensure compliance with, the procedures as set out in the Blood Tests (Evidence of Paternity) Regulations 1971 (SI 1971/1861) (as amended, or any revised version thereof). The procedures deal with the taking of bodily samples, despatch to the tester, testing and reporting to the court. They are designed to ensure that the right people provide the samples, that the same samples reach the tester, and that the nominated tester reports to the court. “As amended” versions of legislation are obtainable through commercial legal publishers.
3. Consent

Testing must not take place unless consent has been obtained in respect of all parties.

There are three types of consent to consider -

1) consent to the bodily material being taken,

2) consent to the material being used and/or stored, and

3) consent to any DNA in the material being analysed and the results used otherwise than for an excepted purpose.

The first requirement is governed by ordinary principles of medical law relating to consent. Reference should be made to the [up to date guidance? DH guidance?] for guidance.

The second and third requirements come from the Human Tissue Act 2004.

The Human Tissue Act requires that when relevant material is used or stored for a scheduled purpose, appropriate consent is obtained.

The purpose of obtaining scientific or medical information about a person (living or deceased) which may be relevant to another person (including a future person) is a scheduled purpose and so appropriate consent must be obtained in relation to that use or storage for that use. It is an offence to use or store relevant material in this way without appropriate consent.

Appropriate consent is explained further below.

Section 45 of the Human Tissue Act 2004 makes it an offence to have any bodily material (i.e. material which has come from a human body and which consists of or contains human cells, including nails, gametes and hair) with intent to:

i.) analyse the DNA in it without obtaining qualifying consent, and

ii) use the results of the analysis otherwise than for certain excepted purposes.

5 Relevant material is material, other than gametes, which consists of or contains human cells, other than embryos outside the body and hair and nails from a living person.

6 Who can give qualifying consent is clearly defined under Schedule 4 to the Human Tissue Act and has different implications depending on whether the person is deceased or living, an adult or a child.
This offence applies to the whole of the UK.

Where appropriate consent has been obtained for relevant material to be used to obtain scientific or medical information about a person which may be relevant to another person, this will be an excepted purpose and so it is not necessary to assess whether qualifying consent has been obtained. However this only applies in relation to England and Wales.

Qualifying consent should be obtained in respect of all parties whose bodily material is to be tested before a paternity test is conducted.

Consent under ordinary medical law principles

3.1 Before a bodily sample is taken from an adult or child in England or Wales it is necessary to ensure that the person’s consent has been obtained. Sometimes it is possible to act without the consent of the person, if, in the case of a child, a person with parental responsibility consents on the child’s behalf, or in the case of an incompetent adult, taking the sample would be in the adult’s best interests. In Scotland, consent can only be given on a child’s behalf if the child lacks the capacity to consent on his or her own behalf. More detail is set out below.

Consent from a child

3.2 In England, Wales and Northern Ireland a child is a person who is under the age of 18 years and in Scotland, a child is a person who is under the age of 16 years.

3.3 The provisions contained within the Mental Capacity Act 2005 should be referred to when considering whether it is lawful to take a sample from a person of 16 or over, in England and Wales, who does not have capacity, within the meaning of that Act.

3.3 In England, Wales and Northern Ireland, a child is considered able to give consent to the taking and use of a sample of their DNA to establish paternity if they are ‘Gillick’ competent, meaning they have sufficient understanding and intelligence to enable them fully to understand what is involved in a proposed medical intervention. In Scotland, a child has legal capacity to consent to medical procedure

7 In England, Wales and Northern Ireland, the Gillick v West Norfolk and Wisbech Area Health Authority case 1985, the court held that a child is considered to be competent to give valid consent to a proposed intervention if they have sufficient intelligence and understanding to enable them fully to understand what is involved.

8 In Scotland, the relevant legislation is Section 2(4) of the Age of Legal Capacity(Scotland) Act 1991, which provides that a person under the age of 16 has legal capacity to consent to
or treatment if, in the opinion of the medical practitioner treating the person, he or she is capable of fully understanding what the treatment will involve.

3.4 In England and Wales, only a person who has parental responsibility for the child, as defined in the Children Act 1989, and in Scotland only a person who has “parental responsibilities and rights” as set out in the Children (Scotland) Act 1995, can consent to the child’s DNA being taken to establish paternity on his or her behalf. Furthermore, section 5 of the Children (Scotland) Act 1995 states that a person can only consent on a child’s behalf if the child lacks capacity. A person without parental responsibilities and rights but with care or control of a child can consent on the child’s behalf to any medical treatment or procedure where the child is not able to give such consent on his or her own behalf, and it is not within the knowledge of the person that a parent of the child would refuse to give the consent in question. The person with parental responsibility should only act in a way which they believe to be in the child’s best interests.

3.5 Decisions concerning whether it is in a child’s best interests to know who their biological father is are not straightforward and any assessment about the child’s welfare must be based on the individual needs of the child in question. Factors, which may be relevant include the possible impact on a child’s sense of identity; the possible impact on the relationship between the child and the putative father and the possible impact on the child’s relationship with those presently perceived as siblings and with those persons undertaking the care of the child.

3.6 Difficulties can arise where a child does not want a sample to be taken. If the child is resisting the sample being taken or is competent to make the decision for themselves and refuses treatment, it may be necessary to seek a declaration from the court as to whether it would be lawful to take the sample.

3.7 In circumstances where a child is considered able to consent to a paternity test being carried out, it is important to make sure that the child has consented voluntarily and has not been unduly influenced by anybody else.

3.8 In addition, where a court has directed that a paternity test be carried out and the person with parental responsibility for the child has refused to consent to the child’s sample being used for the purpose of establishing paternity, the court may waive the requirement for consent where it is satisfied that this is in the best interests of the child.
Consent from an adult

3.9 In England, Wales, no one is able to give consent to a bodily sample being taken from an adult on the adult’s behalf. However, it will be lawful to take such a sample if the person lacks capacity to make a decision for themselves and the practitioner taking the sample considers that it is in the person’s best interests for the sample to be taken. It will be relevant to this assessment whether they person is likely to regain capacity in the near future. If so, it is likely that their best interests will require the procedure to be put on hold until they regain capacity and are able to consent for themselves.

3.10 “Best interests” are not confined to medical considerations, other factors may need to be taken into account including the patient’s values and preferences when competent, their psychological health, well-being, quality of life, relationships with family or other carers, spiritual and religious welfare and their own financial interests.

3.11 Where there is doubt about an individual’s capacity or best interests, the High Court can give a ruling on these matters and on the lawfulness or unlawfulness of a proposed procedure. The duty officer of the Official Solicitor can advise on the appropriate procedure if necessary (full contact details can be found at Annex B).

3.12 In Scotland, where an adult lacks capacity to give consent, a person with appropriate powers appointed under the Adults with Incapacity (Scotland) Act 2000, may consent on the adult’s behalf.

3.13 The Mental Capacity Act 2005 came into force in October 2007. It is necessary to refer to that Act when determining whether it is lawful to take a sample from a person of 16 years or more who lacks capacity, within the meaning of that Act, to consent to the sample being taken.

Disputed Consent

3.14 Those being tested and those giving consent in respect of a child, may wish to seek independent advice – perhaps from a lawyer, a Citizens Advice Bureau or an advice agency – before consenting to the provision of a sample for testing. A number of advice agencies are listed in Annex B.

3.15 Section 5 of the Human Tissue Act 2004 makes it an offence to use or store, without appropriate consent, relevant material in order to obtain scientific or medical information about a living or deceased person which relates to another person (including a future person).

3.16 A person found guilty of committing this offence may be liable to a fine or a term of imprisonment of up to three years or both.

3.17 Appropriate consent for the purpose of section 5 means:
(i) In relation to a living child – the child’s consent, or, where the child is not competent to consent, or the child is competent but they have not made a decision, whether to consent or not to consent, the consent of a person with parental responsibility for the child.

(ii) In relation to a deceased child – if a decision of the child’s to consent or not to consent had been made and not withdrawn before the child died, his consent. If no decision had been made, then the consent of a person who had parental responsibility for the child immediately before the child died. If no one had parental responsibility for the child then the consent of a person who was in a qualifying relationship to the child immediately before the child died.

(iii) In relation to a living adult (16 or over in Scotland) – his consent.

Note that in the third case, if the person lacks capacity to consent to the activity, and there is no decision of his to consent or not to consent to the activity, then consent will be deemed to have been given for the sample to be used or stored for the purpose of obtaining scientific or medical information relevant to another person where the person doing the activity is acting in what he reasonably believes to be the adult’s best interests.

(iv) In relation to a deceased adult (16 or over in Scotland) – if a decision of the adult’s to consent or not to consent had been made and not withdrawn before the adult died, his consent. If no decision had been made and the adult had appointed someone to make decisions in relation to the activity after his death (under section 4 of the Act) then generally that person’s consent must be obtained. In certain circumstances, where no decision has been made by the deceased adult, a person who stood in a qualifying relationship to the adult, immediately before he died, can give the necessary consent.

For further information on appropriate consent, reference should be made to section 3 of the Human Tissue Act 2004 and the Code of Practice on Consent issued under that Act.

**Consent for the purpose of section 45 of the Human Tissue Act 2004 – Non-consensual analysis of DNA**

3.18 Under section 45 of the Human Tissue Act 2004, it is an offence to possess bodily material (except certain excepted material but including hair, nail and gametes) – intending to:

i) analyse its DNA without ‘qualifying’ consent and
ii) use the results of the DNA analysis for a non-excepted purpose.

3.19 In most cases it will have been necessary to obtain appropriate consent for the purpose of using or storing the material for the purpose of obtaining scientific or medical information about a person which is relevant to another person. Where such consent has been obtained use for that purpose will be an excepted purpose when considering section 45 of the Act and so no further consent will be needed. This does not apply in relation to Scotland.

3.20 There are other reasons why a use may be an excepted use. These can be found in Schedule 4 to the Act. The Human Tissue Authority’s Code of Practice on Consent and its guidance on non-consensual DNA analysis explains these purposes in more detail. Some of excepted purposes are as follows:

- the medical diagnosis or treatment of the person from whom the bodily material came;
- use for a specific purpose (known as a Scheduled Purpose) defined in the Human Tissue Act in certain instances;
- prevention or detection of crime;
- functions of a coroner (or procurator fiscal in Scotland);
- conduct of a prosecution;
- purposes of national security;
- implementing an order or direction of a court of tribunal;
- use of tissue from a living person for certain purposes, eg education or training relating to human health, or public health monitoring;
- for tissue existing before 1 September 2006 – use for obtaining medical or scientific information that may be relevant to another person, in certain circumstances, establishing the efficacy of a drug or treatment, research in connection with disorders, or the functioning of, the human body, or transplantation.

What is qualifying consent for the purposes of section 45 of the Human Tissue Act?

3.21 Where qualifying consent is needed it can be given by the same people as set out above in relation to appropriate consent except that in relation to a deceased adult, it is not possible for a person appointed under section 4 of the Act to provide consent.
The role of the sampler

Paternity tests undertaken for legal or other official purposes

3.22 In some civil court cases where there is a dispute about paternity, the court will give a direction under section 20 of the Family Law Reform Act 1969. In those cases, the testing body must be chosen from Ministry of Justice’s accredited list. For these tests, there are Regulations made under section 22 of the 1969 Act which deal with procedures for taking bodily samples, despatching them to the tester and reporting back to the court, that are designed to ensure the process is carried out properly. However, often a court will not give a ‘section 20’ direction but rather request that the parties submit evidence by agreement and in accordance with the case management directions of the court. In such cases, the testing body does not have to be chosen from the accredited list. As with other evidence, it is for the court to consider questions of admissibility and weight of the results of the paternity tests in accordance with the rules of evidence.

3.23 As a general guide, a court will seek assurances that a paternity test, the findings from which will be used as evidence, has been conducted properly with a clear audit trail, which will show that the correct people provided the samples, that those samples reached the testing laboratory, that the testing laboratory was competent to carry out the tests, and the results relating to the samples then reached the court.

3.24 It is strongly recommended that persons involved in commissioning a paternity test appoint an independent sampler to collect and verify samples as it is the best way of ensuring the authenticity of the paternity test.

3.25 There are other circumstances where it is necessary to have a robust chain of evidence and to ensure that the testing laboratory is competent, for example, re-registrations of birth.

3.26 Independent samplers must not be related to the sample giver, nor have any financial or personal interest in the outcome of the paternity test. Often people choose to ask a GP or nurse to take and verify samples on their behalf.

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9 Whilst there is no mention of DNA in the Births and Deaths Registration Act 1953, which relates to England and Wales, re-registration under sections 10A or 14 of the Act requires parents to sign a declaration relating to the paternity of the child. The declaration contains a statement that any person whom deliberately gives false information for the registration of a birth may be prosecuted. Please note that the law in Scotland and in Northern Ireland differs in this area. The relevant legislation in Scotland is the Registration of Births, Deaths and Marriages (Scotland) Act 1965 and in Northern Ireland it is the Births and Deaths Registration (NI) Order 1976. For further information about paternity and re-registrations of birth in England and Wales, please contact the Office of National Statistics. For queries relating to Scotland, please contact the General Register Office for Scotland and for those relating to Northern Ireland, the Department of Finance and Personnel. Full contact details can be found at Annex B.
Home paternity kits

3.27 Many people might prefer to conduct a test without involving an outside party, preferring to take and verify the samples themselves. In such circumstances, they may choose to purchase a paternity test which is not intended for use in court. Such tests are often marketed as ‘peace of mind’ tests or ‘home paternity kits’.

3.28 As with all paternity tests, it is vital that all parties samplers are satisfied that proper consent to testing has been given before a sample is taken.

3.29 In circumstances where a child is to be tested, the needs of the child should be a key concern. Where possible, after taking into account the age and maturity of the child or young person, the independent sampler or parent should obtain and take into consideration their views when reaching a decision on whether to undertake a test. A sample should not be obtained or a test undertaken if the independent sampler or the provider of the testing service has reason to believe that this would be contrary to the best interests of the child or young person.

3.30 It will not always be possible for the independent sampler – whatever their relation to the child or young person – to obtain a balanced appraisal of the issues involved in their welfare. However, it is a key principle of this Good Practice Guide that the best interests of the child should be a primary concern when commissioning all genetic paternity tests, be they for legal or private reasons.

3.31 In order to reinforce this message, we recommend that providers of genetic testing services provide their samplers with clear user instructions in line with paragraphs 1.7 and 1.8 of this Guide. In addition, genetic paternity testing services must not be supplied solely at the request of those under the age of 16.

For more information about the authenticity and integrity of samples, please see Section 4.

'Motherless' testing

3.32 By ‘motherless’ testing, we refer to the practice whereby the paternity of a child – who, under UK law, is not deemed to be capable of consenting to their sample being analysed for that purpose – is undertaken without the knowledge of the mother.

3.33 The best interests of the child should be a primary concern when commissioning genetic paternity tests. This Guide reflects the view of the Human Genetic Commission that, in the majority of circumstances, motherless testing could prove harmful to the child, as well as to the family unit as a whole.

3.34 The British Medical Association advises doctors who are consulted by putative fathers about paternity testing without the mother's knowledge and consent to encourage those seeking testing to discuss their plans with the child’s mother. Should
The Good Practice Guide on Paternity Testing Services

the putative father reject this advice, the British Medical Association tells doctors not to become involved in the testing process.

3.35 We are aware too that, in cases where parentage is disputed, the Child Support Agency may offer genetic testing of all three parties - the child, the mother and the alleged father. It is unlikely that the Child Support Agency will accept motherless testing as a method of resolving a paternity dispute for the foreseeable future.

3.36 We are therefore of the view that motherless testing should not be undertaken by paternity testing companies, unless such a test has been directed by a court.

To comply with this Good Practice Guide paternity testing companies must not:

- actively promote the motherless testing of children in their advertising, marketing and customer information material.
- undertake paternity tests intended for private reasons, i.e. using ‘home kits’ or ‘peace of mind’ tests, without the mother’s knowledge, even if she declines to be tested herself.

Prenatal paternity testing

3.37 Paternity tests carried out during pregnancy have begun to be offered by several paternity testing companies and the market for prenatal tests has the potential to grow. The development and availability of prenatal paternity testing raises new reproductive dilemmas for some pregnant women and their partners.

3.38 Some companies offer paternity tests during pregnancy based on the collection of fetal tissue or on a maternal blood test. The nature of these tests, the way they are undertaken and the accuracy of the results mothers can expect will vary. What is more, some prenatal paternity tests are invasive and involve risks up to and including miscarriage. It is vitally important therefore, that testing companies offering prenatal paternity tests direct pregnant mothers to their GP or midwife before proceeding with a prenatal paternity test, not only because of the health risks to the mother and baby but also so that independent counselling be made available for those considering prenatal paternity testing where necessary.

3.39 Such a test might be used by a pregnant woman deciding whether to proceed with a pregnancy. Knowing the identity of the genetic father of the fetus could significantly influence her decision. However, under the Human Tissue Act 2004, any
such test undertaken in the UK must be conducted with the necessary consent (to the
taking of the sample and the testing of it) of the man or men in question. We share the
Human Genetics Commission’s concern that tests ordered over the internet or by post
might be undertaken without the consent of all whose DNA is to be tested. We
support their recommendation that consumers of prenatal paternity tests should be
made fully aware of the requirements for consent under the terms of the Human Tissue
Act by the companies offering these tests.
4. **Authentication of samples**

All samples to be tested must be supported by a reliable mechanism to establish and maintain the authenticity and integrity of the sample.

**Paternity tests which may be admissible as evidence in court**

4.1 As we have explained in Section 3, a court of law may direct, in the course of a case, that a test be undertaken to establish paternity. However, often a court will not direct that a test be undertaken but rather request that parties submit DNA evidence by agreement and in accordance with the case management directions of the court. As with other evidence, it is for the court to consider questions of admissibility and weight and, in considering these questions, the court is likely to examine whether for each sample that is tested, the identity of the provider of the sample can be established and maintained.

The sampler must be an independent party. In other words, he or she should not be related to the sample giver, nor have any financial or personal interest in the outcome of the paternity test.

Any method used to verify that samples relate to donors must be clear, robust and capable of being maintained. One common method requires each person being tested (including all children of whatever age) to provide two passport-sized photographs for identification purposes. These photographs should be surrendered to the sampler and retained for identification purposes with the samples. The sampler must sign that the photographs are a true likeness to the donor of the sample.

The photographs may form an integral part of a reliable “audit trail” linking the sample with the donor. This may be particularly helpful in circumstances where a dispute arises once the test has been undertaken.

Required levels of training and competence for those taking samples should be incorporated into the standard operating procedures or operating requirements of the supplier. (See ‘Section 3 – Consent’ for more information about the role of the sampler.)

Samplers must use materials or kits supplied by organisations conducting tests. This may be important for a number of reasons including for validation and quality assurance purposes.
4.2 It should be noted that additional measures may be required for criminal cases, for example to meet the requirements of the Police and Criminal Evidence Act 1984. Such measures are beyond the scope of this document.

Tests intended for private use.

4.3 In some circumstances, parties may wish to establish paternity for their own information and will not intend for the test results to be used in court. Some paternity tests which are now available to buy over-the-counter or via the internet or by visiting walk-in DNA testing centres are not intended for use in court. Such tests are often marketed as ‘peace of mind’ tests or ‘home testing kits’.

4.4 We recognise that some people might prefer to conduct a test without involving an outside party. Further, we are aware that tests intended for private purposes involve less administration for testing companies and therefore can be marketed at a much cheaper price. However, consumers should be aware that disputes concerning paternity may lead to court proceedings and a court may be unwilling to admit the results of a test which has not met all the requirements set out in the above section. Therefore, unless consumers are resolute that they will have no intention to use the test results for legal or other official reasons, it could be a false economy for them to buy a cheap paternity test.

4.5 Ideally, tests intended for private use should be carried out to the same rigorous requirements as tests designed for use in court or for other official reasons, i.e. using an independent sampler. In the absence of an independent sampler, there are some measures, which companies must adopt to serve to authenticate the sample and protect the interests of parties commissioning the test.
These measures are:

- to always request samples from the mother, child and putative father, i.e. to refuse motherless testing for home tests.

- to include as part of the advertising, marketing and kit literature, information which will prompt people to consider the future implications for themselves and their families, of commissioning a test. Companies should make people aware that the best interests of any children who may be involved must be carefully considered and that results can sometimes be unexpected and involve future legal implications.

- to make clear in the advertising and marketing of a private paternity test that its results might not be admissible as evidence in a court of law or for other official purposes.

- to make clear that it is necessary to obtain the consent of any person, or their parent where appropriate, in order to touch them to obtain a bodily sample, and that reference can be made to this Good Practice Guide for further detail.

- to make clear in the advertising, marketing and kit literature that under the Human Tissue Act 2004, it is an offence, punishable by a fine or up to three years imprisonment, or both, to:

  (i) have bodily material with the intention of analysing human DNA without qualifying consent and use it otherwise than for an excepted purpose, or

  (ii) use or store bodily material without appropriate consent for the purpose of obtaining scientific or medical information about the person whose material is being used or stored, which may relate to another person.
5. Confidentiality and Storage of Samples and Records

 Suppliers have a common law duty of confidence in respect of all the parties to the test.

The storage and security of samples and data should be such as to ensure confidentiality and should be in accordance with the Data Protection Act 1998. Suppliers should inform all parties giving consent to a paternity test of their procedures for ensuring that data remains confidential and that they are working within the legal and ethical framework set out in the NHS Confidentiality Code of Practice (2003) and the NHS Scotland Code of Practice on Protecting Patient Confidentiality (2003).

Disclosure of test results will generally only be made to parties to the test and authorised third parties - for example the Child Support Agency in the case of tests arranged through that Agency. For further information please see Annex B. However, test results may be disclosed where this is in the public interest and where the Data Protection Act 1998 will not be breached.

Before obtaining samples and personal information from those being tested, suppliers should inform the customer of their procedures for the secure storage and disposal of samples and records.

 Suppliers should test samples and use identifiable data only for those purposes for which consent has been given.

All staff (including subcontractors) with access to samples or data should be bound by a code of confidentiality.

Samples and records should be retained for periods consistent with the nature of the test and the purposes to which the results are likely to be put.

Confidentiality

5.1 A duty of confidence arises when one person discloses information to another (e.g. patient to clinician) in circumstances where it is reasonable to expect that the information will be held in confidence. It:

- is a legal obligation that is derived from case law and more recently from the European Convention on Human Rights;
- is a requirement established within professional codes of conduct; and
• Must be included within employment contracts as a specific requirement linked to disciplinary procedures.

5.2 This is especially pertinent to organisations that provide genetic paternity testing services. Consequently, confidential personal information, must not be used or disclosed for purposes other than paternity testing without the individual’s explicit consent, some other legal basis, or where there is a robust public interest or legal justification to do so.

**Data Protection Act 1998**

5.3 The Data Protection Act 1998 applies to all personal information processed by organisations. DNA is personal data, therefore, organisations have a responsibility to ensure that any databases containing information related to individuals whether processed or stored on computer or in a manual filing system, are kept and processed in accordance with the data protection principles as set out in the Data Protection Act. This applies whether the database is structured either by reference to individuals or by reference to criteria related to individuals.

5.4 Information about the Data Protection Act 1998 can be obtained from the Office of the Information Commissioner who is responsible for regulating the Act.

5.5 In line with the Data Protection Act 1998, specimens and records should not be retained longer than is necessary for the purpose for which they were collected. The ability to recheck in cases where the test result is challenged is the only valid reason for suppliers to retain samples/data in an individually identifiable form. In the interests of security and of reducing the risk of unintended disclosure of confidential information, organisations should have in place protocols to regularly review the retention of samples and supporting data.

**NB.** All parties to the test should be aware that this Good Practice Guide may not apply in respect of tests that are undertaken as a part of investigations into alleged criminal offences. For more information about the retention of personal data, please contact the Information Commissioner’s Office, details of which can be found at Annex B.
Annex A:

**Glossary of Terms**

Some of the terms and abbreviations used in this Guide might not known to you, so we have included a glossary of terms and abbreviations for your information.

**Commissioner** - An organisation or member of the public that contracts with a supplier for the provision of a genetic paternity test.

**Deoxyribonucleic Acid (DNA)** is found in almost all of the cells that make up the human body. DNA contains a code that determines the characteristics of a person. No two people in the world have exactly the same DNA except for identical twins. Samples of DNA can be used to establish whether individuals are related.

**Parties to the Test** – persons being tested or providing samples for a scientific test.

**Paternity Testing** – Modern paternity testing compares the genetic patterns (commonly, these days, the DNA) of the mother, a man and the child to predict with a high level of accuracy whether or not the man is the biological father of the child in question.

**Sampler** - A person who takes a sample, on behalf of a supplier, for testing purposes.

**Supplier** - The provider of a genetic paternity testing service.

**UKAS** - United Kingdom Accreditation Service.
Annex B:

Organisations for further information, advice, personal and family support [This Annex is to be updated and finalised following stakeholder consultation]

Citizen’s Advice Bureau
There is a local Citizen’s Advice Bureau in most towns. Details can be found in the telephone directory and on their website – www.citizensadvice.org.uk

Child Support Agency
National Enquiry Line 08457 133 133.
Minicom 08457 138 924.
(Lines are open 8am to 8pm Monday to Friday and 9am to 5pm Saturday).
Website www.csa.gov.uk
Useful guidance may also be found in leaflet CSL 110 - "Child Support: Disputed parentage and DNA testing".

Information Commissioner
The Information Commissioner’s Office
Wycliffe House, Water Lane
Wilmslow
Cheshire
SK9 5AS

Helpline 08456 306060 (Lo-Call Rate) 01625 524510 (National Rate)
Switchboard 01625 545700
Website www.ico.gov.uk

In addition to their head office in Wilmslow, the Information Commissioner’s Office also has offices in Scotland, Wales and Northern Ireland. If you would prefer to contact one of these offices, please visit the Information Commissioner’s Office website for full contact details.

The Ministry of Justice
For information about the Ministry of Justice’s accredited list, contact:
Family Relationships Branch 2
Family Justice Division
HMCS, 4th Floor, Selborne House
54-60 Victoria Street
London SW1E 6QW
The Good Practice Guide on Paternity Testing Services

Enquiry line 020 7210 2653
Email paternity.enquiries@hmcourts-service.gsi.gov.uk

The Medicines and Healthcare products Regulatory Agency (MHRA)
Information Centre
10-2 Market Towers
1 Nine Elms Lane
London
SW8 5

Telephone 020 7084 2000
Email info@mhra.gsi.gov.uk
Website www.mhra.gov.uk

In Scotland

Scottish Child Law Centre
54 East Crosscauseway
Edinburgh
EH8 9HD

Telephone 0131 667 6333
Website www.sclc.org.uk

Contact for family law in Scotland:

Scottish Executive Justice Department
Civil Justice, Law Reform and International Division
2W, St Andrews House
Regent Road
Edinburgh
EH1 3DG

For policy on genetic paternity testing:

Scottish Executive Health Department
Directorate of Health Improvement
St Andrews House
Regent Road
Edinburgh
EH1 3DG
### Annex C:

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<tr>
<th><strong>KEY CHANGE</strong></th>
<th><strong>IMPLICATION FOR NEW GUIDANCE</strong></th>
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<tr>
<td>The introduction of the Human Tissue Act 2004 and the Human Tissue Authority’s Code of Practice on Consent, which came into force on the 1st September 2006.</td>
<td>It is vital that the new guidance reflects changes in the law in respect of the Human Tissue Act 2004. The Act and its accompanying Code of Practice, sets out new legislation in respect of the collection and storage of all human tissue, including DNA.</td>
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<td>In relation to paternity testing, the most important aspect of the Act is the new ‘DNA theft’ offence contained in it, which means it is now an offence to possess bodily material (material from a human body that contains human cells) with the intention of analysing the DNA and using the results otherwise than for an excepted purpose without qualifying consent.</td>
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<td>The new guidance explains how the Act affects paternity testing and emphasises the need for all parties (companies, children, parents and putative parents) to obtain appropriate consent.</td>
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<td>The Review, conducted in 2006, of the Ministry of Justice’s list of bodies accredited to carry out a court-directed test under s20 of the Family Law Act 1969.</td>
<td>In some civil court cases where there is a dispute about paternity, the court will give a direction under section 20 of the Family Law Reform Act 1969. In those cases, the testing body must be chosen from Ministry of Justice’s accredited list. For these tests, there are Regulations made under section 22 of the 1969 Act which deal with procedures for taking bodily samples, despatching them to the tester and reporting back to the court, that are designed to ensure the process is carried out properly. As with other evidence, it is for the court to consider questions of admissibility and weight of the results of the paternity tests in accordance with the rules of evidence.</td>
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<td>Other Government departments (such as the Child Support Agency and the Office of...</td>
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National Statistics) have tended to refer to the MoJ list of companies as a list of ‘officially’ reputable companies in the paternity testing market.

Last year, the Ministry of Justice reviewed their policy relating to the accreditation list following concerns that the Department was seen as having responsibility for DNA testing generally. They concluded that, whilst they would continue to maintain the accreditation list, its application would be strictly limited to the legal remit as set out in section 20. There are currently 6 testing companies listed.

The new Guide makes explicit the MoJ’s limited role in the paternity testing market and reminds companies that accreditation if they do not comply with MoJ’s strict criteria.

<table>
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<th>Changes in and expansion of the private paternity testing market since 2001.</th>
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<td>The private paternity testing market has expanded and adapted in recent years. For example, we have seen a growth in the number of companies offering products such as home paternity kits, which tend to be cheaper than those used for official purposes and the introduction of ‘walk-in’ testing centres. The new guidance recognises that some people might prefer to conduct a test without involving an outside party and seeks to advise consumers on how best to do this within the new legal framework created by the Human Tissue Act.</td>
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