Research: The role and responsibility of doctors

February 2002

Good Practice in Research

This guidance sets out the standards expected of all doctors working in research in the NHS, universities and the private sector or other circumstances. It develops the general principles and standards on research set out in our other guidance documents and should be used in conjunction with them.

You must always follow the principles in this guidance and take note of other governance and good practice guidelines issued by the Departments of Health and other authoritative bodies. You must observe and keep up to date with the laws and statutory codes of practice which affect your work.

Contents

Introduction

Scope of the guidance

Principles governing research practice

Putting the principles into practice

Protecting the autonomy and interests of participants
Research design
Conflicts of interests

Funding and payments

Consent

Valid consent

Consent for research

Seeking consent to obtain organs, tissues or body fluids

Post mortems

Confidentiality

Use of existing records in research

Obtaining consent

Where consent cannot be obtained

Projects which are not approved by research ethics committees

Disclosures in the public interest

Records made during research

Recording and reporting research results

Situations requiring special consideration

Vulnerable adults

Assessing capacity

Fluctuating capacity

Adults who lack capacity

Advance statements

Research into treatment in emergencies

Children and young people

Teaching, training and management

Teaching and supervision
Introduction

1. Research involving people directly or indirectly is vital in improving care for present and future patients and the health of the population as a whole.

2. Doctors involved in research have an ethical duty to show respect for human life and respect peoples' autonomy. Partnership between participants and the health care team is essential to good research practice and such partnerships are based on trust. You must respect patients' and volunteers' rights to make decisions about their involvement in research. It is essential to listen to and share information with them, respect their privacy and dignity, and treat them politely and considerately at all times.

Scope of the guidance

3. Research in this document refers to any experimental study into the causes, treatment or prevention of ill health and disease in humans, involving people or their tissues or organs or data. It includes toxicity studies, clinical trials, genetic studies, epidemiological research including analyses of medical records, and other collections and analyses of data about health and illness, whether anonymised or not. It covers clinical research which may be therapeutic, that is of potential benefit to patients who participate, and non-therapeutic, where no immediate benefit to those patients or volunteers who participate is expected.

4. This guidance does not apply to clinical audit which involves no experimental study. Nor does it cover innovative therapeutic interventions designed to benefit individual patients. These activities are covered by the standards and principles set out in our other guidance.

Principles governing research practice

5. Because the benefits of the research are not always certain and may not be experienced by the participants, you must be satisfied that the research is not contrary to their interests. In particular:
   - you must be satisfied that, in therapeutic research, the foreseeable risks will not outweigh the potential benefits to the patients. The development of treatments and furthering of knowledge should never take precedence over the patients' best interests;
   - in non-therapeutic research, you must keep the foreseeable risks to participants as low as possible. In addition the potential benefits from the development of treatments and furthering of knowledge must far outweigh any such risks;
   - before starting any research you must ensure that ethical approval has been obtained from a properly constituted and relevant research ethics committee - such committees abide by the guidance for local and multi-centre research ethics committees\(^1\), whether they are within the NHS, the university sector, the pharmaceutical industry, or elsewhere\(^2\);
   - you must conduct research in an ethical manner and one that accords with best practice;
o you must ensure that patients or volunteers understand that they are being asked to participate in research and that the results are not predictable;

o you must obtain and record the participants’ consent; save in exceptional circumstances where specific approval not to obtain consent must have been given by the research ethics committee;

o respect participants’ right to confidentiality;

o with participants’ consent, keep GPs, and other clinicians responsible for participants’ care, informed of the participants’ involvement in the research and provide the GPs with any information necessary for their continuing care;

o you must complete research projects involving patients or volunteers, or do your best to ensure that they are completed by others, except where results indicate a risk that participants may be harmed or no benefit can be expected;

o you must record and report results accurately;

o you must be prepared to explain and justify your actions and decisions.

6. If you undertake records based research which does not involve patients or volunteers directly you are still bound by the principles on which this guidance is based. You must be satisfied that you have appropriate authority to access any identifiable data; advice on access to, and use of, data is in paragraphs 30 to 42 below.

7. The principles set out in our guidance Good Medical Practice, Consent: patients and doctors making decisions together and Confidentiality: Protecting and Providing information must be followed when undertaking research.

Putting the principles into practice

Protecting the autonomy and interests of participants

8. You must conduct all research with honesty and integrity and, in designing, organising and executing research, you must always put the protection of participants’ interests first. You must:

o not put pressure on patients or volunteers to participate in the research;

o ensure that no real or implied coercion is used on participants who are in a dependent relationship to you, for example, medical students, a junior colleague, nurse in your practice or employee in your company;

o keep to all aspects of the research protocol and make significant changes to, or deviations from, the protocol only with the agreement of the research ethics committee and the research funder.

9. If you have good reason to believe that participants are being put at risk by participating in the research or by the behaviour of anyone conducting the research, you should report your concerns to a senior colleague. If you remain concerned, you should inform the research ethics committee, and the research sponsor together with the employer or contracting body if appropriate.

10. You must report evidence of financial or scientific fraud or other contravention of this guidance to an appropriate person or authority, including where appropriate the GMC or other statutory regulatory body.

Research Design

11. All research must be based on a properly developed protocol that has been approved by a research ethics committee. It must be prepared according to the good practice
guidelines given in this guidance and that of other relevant bodies, for example, the Departments of Health, Royal College of Physicians of London and the Medical Research Council, and where appropriate, the International Conference on Harmonisation.

12. You must ensure that:
   o the aims, design and methodology of the project are justifiable, verifiable and scientifically valid;
   o over-use of patient groups or individuals is avoided.

Conflicts of interest

13. You must always act in the participants’ best interests when carrying out research. You must ensure that your judgement about the research is not influenced, or seen by others to be influenced, by financial, personal, political or other external interests at any stage of the process. You should always declare any conflicts that may arise to an appropriate person, authority or organisation, as well as to the participants.

Funding and payments

14. You must be open and honest in all financial and commercial matters relating to your research and its funding. In particular you must:
   o declare to research ethics committees, prior to the research being approved, all financial interests and sums of money which you know, or estimate, will be paid for the research undertaken; accept only those payments and benefits approved by the research ethics committee;
   o give participants information on how the research is funded, including any benefits which will accrue to researchers and/or their departments;
   o respond honestly and fully to participants’ questions, including inquiries about direct payments made to you and any financial interests you have in the research project or its sponsoring organisations;
   o ensure that everyone in the research team, including nurses and non-medical staff, is informed about the way in which the research is being financed and managed;
   o not offer payments at a level which could induce research participants to take risks that they would otherwise not take, or to volunteer more frequently than is advisable or against their better interests or judgement;
   o not allow your conduct in the research to be influenced by payment or gifts.

Consent

15. Seeking consent is fundamental to research involving people.

Valid consent

16. Participants’ consent is legally valid and professionally acceptable only where participants are competent to give consent, have been properly informed, and have agreed without coercion.
Consent for research

17. Obtaining consent is a process involving open and helpful dialogue, and is essential in clarifying objectives and understanding between doctors and research participants.

18. Effective communication is the key to enabling participants to make informed decisions. When providing information you must do your best to find out about participants' individual needs and priorities. For example, participants' current understanding of their condition and treatment, beliefs, culture, occupation or other factors may have a bearing on the information they require. You must not make assumptions about participants' views, but discuss matters with them, and ask whether they have any concerns about the treatment or the risks involved in the research programme.

19. You must ensure that any individuals whom you invite to take part in research are given the information which they want or ought to know, and that is presented in terms and a form that they can understand. You must bear in mind that it may be difficult for participants to identify and assess the risks involved. Giving the information will usually include an initial discussion supported by a leaflet or sound recording, where possible taking into account any particular communication or language needs of the participants. You must give participants an opportunity to ask questions and to express any concerns they may have.

20. The information provided should include:

- what the research aims to achieve, an outline of the research method, and confirmation that a research ethics committee has approved the project;
- the legal rights and safeguards provided for participants;
- the reasons that the patient or volunteer has been asked to participate;
- if the project involves randomisation, the nature of the process and reasons for it, and the fact that in double-blind research trials neither the patient nor the treatment team will know whether the patient is receiving the treatment being tested or is in the control group;
- information about possible benefits and risks;
- an explanation of which parts of the treatment are experimental or not fully tested;
- advice that they can withdraw at any time and, where relevant, an assurance that this will not adversely affect their relationship with those providing care;
- an explanation of how personal information will be stored, transmitted and published; · what information will be available to the participant about the outcome of the research, and how that information will be presented;
- arrangements for responding to adverse events;
- details of compensation available should participants suffer harm as a result of their participation in the research.

21. You must allow people sufficient time to reflect on the implications of participating in the study, and provide any further information they request, including a copy of the protocol approved by the research ethics committee. You must not put pressure on anyone to take part in the research. You should make a record of the discussion and the outcome.

22. When seeking consent it is also important to consider the needs of particular groups of people and situations that require special consideration, advice is given in paragraphs 43 to 58.
Seeking consent to obtain organs, tissues or body fluids from living patients or volunteers

23. Samples of body fluids, tissues and organs can form a valuable archive for research purposes. You must obtain appropriate consent or authorisation before taking or retaining organs, tissues or body fluids, from patients or volunteers, for research purposes. This applies whether the material is obtained solely for research purposes or retained following a clinical or surgical treatment.

24. When seeking participants’ consent, you must be satisfied that participants understand the amount and nature of tissues, organs or body fluids which will be taken. Where material is being obtained for a specific project, you must explain how the sample will be used; where a sample is to be stored and used in further research projects, this must be made clear. You must be prepared to respond honestly and sensitively to any questions which the participants may ask.

25. You must be open and honest about any financial transactions associated with the use of tissues, organs or body fluids (see paragraph 14). Financial remuneration for supplying such material to other organisations or individuals should be limited to administrative costs involved, and you should not be involved, directly or indirectly, in buying or selling human organs, tissues or body fluids.

26. Obtaining human organs, tissue and body fluids for use in research raises complex issues, and you must ensure that you take account of the relevant guidance. Professional guidance on post-mortem examinations, and the removal and retention of human material has been issued by a number of bodies; advice from the UK Health Departments is in preparation (see Appendix).

Post-mortems

27. The legislation relating to post-mortems and retention of organs is currently being reviewed in the UK. You must keep up to date with and observe the law which governs this area of practice

28. Different legal requirements arise in post-mortems undertaken at the direction of the coroner or procurator fiscal, from those undertaken at the instigation of the hospital. Nonetheless in all cases it is essential that the deceased’s relatives are involved in the decision if it is planned to remove and retain any tissue, body fluids or organs for the purposes of research:

- where a child has died, the parental consent to the removal, storage and use of such material for research must be obtained;
- where an adult has died, reasonable efforts should be made to ascertain what the person would have wanted, for example by discussing the issues with their relatives or representatives, and reading any 'living will' or other statements made by that person.

29. It is essential that clear information is provided to the family or representatives of a deceased patient about the extent of the tissue and fluid or organs to be taken, and as far as possible, the nature of the research for which it will or may be used. You must be prepared to respond honestly and sensitively to any questions that they may ask and you should be considerate when giving information to and obtaining consent from them.

Confidentiality

30. Patients and people who volunteer to participate in research are entitled to expect that doctors will respect their privacy and autonomy. Where data is needed for research, epidemiology or public health surveillance you should:

1. Seek consent to the disclosure of any information wherever that is practicable;
2. Anonymise data where unidentifiable data will serve the purpose;
3. Keep disclosures to the minimum necessary;
4. Keep up to date with, and abide by, the requirements of statute and common law, including the Data Protection Act 1998 and orders made under the Health and Social Care Act 2001.

Use of existing records in research

Obtaining consent

31. Records made for one purpose, for example the provision of care, should not usually be disclosed for another purpose without the patient’s consent. If you are asked to disclose, or seek access to, records containing personal information for research, you must be satisfied that express consent has been sought from the participant, wherever that is practicable.

32. Where it is not practicable for the person who holds the records either to obtain express consent to disclosure, or to anonymise records, data may be disclosed for research, provided participants have been given information about access to their records, and about their right to object. Any objection must be respected. Usually such disclosures will be made to allow a person outside the research team to anonymise the records, or to identify participants who may be invited to participate in a study. Such disclosures must be kept to the minimum necessary for the purpose. In all such cases you must be satisfied that participants have been told, or have had access to written material informing them:

   o that their records may be disclosed to persons outside the team which provided their care.
   o of the purpose and extent of the disclosure, for example, to produce anonymised data for use in research, epidemiology or surveillance.
   o that the person given access to records will be subject to a duty of confidentiality.
   o that they have a right to object to such a process, and that their objection will be respected, except where the disclosure is essential to protect the patient, or someone else, from risk of death or serious harm.

33. Where you control personal information or records about patients or volunteers, you must not allow anyone access, unless the person has been properly trained and authorised by the health authority, NHS trust or comparable body and is subject to a duty of confidentiality in their employment or because of their registration with a statutory regulatory body.

Where consent cannot be obtained

34. Where it is not practicable to contact participants to seek their consent to the anonymisation of data or use of identifiable data in research, this fact should be drawn to the attention of a research ethics committee so that it can consider whether the likely benefits of the research outweigh the loss of confidentiality to the patient. Disclosures may otherwise be improper, even if the recipients of the information are registered medical practitioners. The decision of a research ethics committee would be taken into account by a court if a claim for breach of confidentiality were made, but the court’s judgement would be based on its own assessment of whether the public interest was served.
Projects which are not approved by research ethics committees

35. Some epidemiology, health surveillance and monitoring is, for good reason, undertaken without research ethics committee approval. Data can be used in these cases where there is a statutory requirement to do so, for example where the data relates to a known or suspected 'notifiable' disease, or where there is a relevant order under the Health and Social Care Act 2001.

36. Where there is no statutory duty to disclose information, disclosures must be made in accordance with the principles set out in paragraph 30 above. Where it is not practicable to seek consent, nor to anonymise data, information may be disclosed or accessed where the disclosure is justified in the public interest.

Disclosures in the public interest

37. Personal information may be disclosed in the public interest, without the individual’s consent, where the benefits to an individual or to society of the disclosure outweigh the public and the individual’s interest in keeping the information confidential. In all cases where you consider disclosing information without consent from the individual, you must weigh the possible harm (both to the individual, and the overall trust between doctors and participants) against the benefits which are likely to arise from the release of information.

38. Before considering whether disclosure of personal information would be justified, you must be satisfied that:
   a. the participants are not competent to give consent; or,
   b. it is not practicable to seek consent, for example because:
      o the records are of such age and/or number that reasonable efforts to trace patients are unlikely to be successful;
      o the patient has been or may be violent;
      o action must be taken quickly (for example in the detection or control of outbreaks of some communicable diseases) and there is insufficient time to contact participants; or
   c. participants have been asked, but have withheld consent.

39. In considering whether the public interest in the research outweighs the privacy interests of the individual and society, you will need to consider the nature of the information to be disclosed, how long identifiable data will be preserved, how many people may have access to the data, as well as the potential benefits of the research project. A participant’s wishes about the use of data can be overridden only in exceptional circumstances and you must be prepared to explain and justify such a decision.

40. Other circumstances in which disclosures may be made without consent are discussed below.

Records made during research

41. Records made during research should be kept securely and disclosed to people outside the research team only in accordance with the guidance in our booklet Confidentiality: Protecting and Providing Information.

Recording and reporting research results

42. When you are involved in a research project you must:
- maintain complete and accurate records and retain them for purposes of audit;
- record and report research results accurately and in a way that is transparent and open to audit;
- report adverse findings as soon as possible to the research participants who are affected, to those responsible for their medical care, to the research sponsor and primary funder and to bodies responsible for protecting the public, such as the Medicines Control Agency or other licensing bodies;
- make every effort to inform participants of the outcome of the research; or make the information publicly available if it is not practicable to inform individual participants;
- ensure that claims of authorship are justified;
- publish results whenever possible, including adverse findings, preferably through peer reviewed journals. You must always try to ensure that your research results appear in such journals before they are reported in other media, and if you are presenting your research findings to the non-medical press you should make every effort to ensure that your research findings are reported in a balanced way.
- explain to the relevant research ethics committee if, exceptionally, you believe there are valid reasons not to publish the results of a study.

People and situations requiring special consideration

Vulnerable adults

43. Competent but vulnerable adults may find it difficult to withhold consent if they are put under implicit or explicit pressures from institutions or health care professionals. But the treatments being researched might be of significant benefit to such people, and to exclude vulnerable groups could be a form of discrimination. Frail elderly people, people living in institutions and adults with learning difficulties or mental illness who remain competent should all be considered vulnerable. Pregnant women may also be subjected to hidden pressures to become involved in research, and their inclusion in a project may need special consideration.

44. Careful consideration should therefore be given to involving vulnerable adults in research, and particular attention should be given to the consent process, ensuring that they have sufficient information provided in a suitable format, and enough time to consider the issues. You should give consideration to their vulnerability and difficulties they may have in understanding or retaining information. You may need to encourage them to seek the help of a relative/close friend, support worker/advocate. You should proceed with the research only if you believe that the participant's consent is voluntary and based on an understanding of the information they have been given.

Assessing capacity

45. No one can give or withhold consent on behalf of an adult with mental incapacity. Before involving participants who, by reason of mental disorder or inability to communicate, lack mental capacity, you must first assess their capacity to make an informed decision about participating in research.
Fluctuating capacity

46. Where participants have difficulty retaining information, or are only intermittently competent to make a decision, you should provide any assistance they might need to reach an informed decision. You should record any decision made while they were competent, including the key elements of the consultation. You should review any decision made whilst they were competent at appropriate intervals before the research starts, and at intervals during the study, to establish that their views are consistently held and can be relied on.

Adults who lack capacity

47. In England, Wales and Northern Ireland there is no legislation setting out the circumstances in which research involving adults with mental incapacity may be undertaken.

48. Research into conditions that are not linked to incapacity should never be undertaken with adults with incapacity if it could equally well be done with other adults. It should be limited to areas of research related to the participants' incapacity or to physical illnesses that are linked to their incapacity. If you involve this group of people in research you must demonstrate that:

- it could be of direct benefit to their health; or
- it is of special benefit to the health of people in the same age group with the same state of health; or
- that it will significantly improve the scientific understanding of the adult's incapacity leading to a direct benefit to them or to others with the same incapacity; and
- the research is ethical and will not cause the participants emotional, physical or psychological harm; and
- the person does not express objections physically or verbally.

49. You must also ensure that participants' right to withdraw from the research is respected at all times. Any sign of distress, pain or indication of refusal irrespective of whether or not it is given in a verbal form should be considered as implied refusal.

Advance Statements

50. If you are involving adults who have lost capacity to consent to, or refuse to participate in research, for example through onset or progress of a mental disorder, you should try to find out whether they have previously indicated preferences in an advance statement (‘advance directives’ or ‘living wills’). Adults can express their wishes about forms of treatment and about participation in research in an advance statement and their views should be taken into account. Any refusal to participate in a research trial or project, given when an adult patient was competent, which remains valid and clearly applicable, is legally binding and must be respected.

Research into treatment in emergencies

51. In an emergency where consent cannot be obtained, treatment can be given only if it is limited to what is immediately necessary to save life or avoid significant deterioration in the patient’s health. This may include treatment that is part of a therapeutic research project, where the risks of the new treatment are not believed to exceed the known risks of standard treatment. If, during treatment, the patient regains capacity, the patient
should be told about the research as soon as possible and their consent to continue should be sought.

52. If it is possible, you should discuss the situation with relatives and/or partners of the patient unless you have what you judge to be good reason to believe that the patient would wish otherwise.

53. You must always respect the terms of any valid advance refusal that you know about, or is drawn to your attention.

54. If there is time, you may want to seek the opinion or advice of another member of the research team to discuss the course of action you are intending to take.

Children and young people

55. Research involving children and young people is important in promoting their health and to validate in them the beneficial results of research conducted with adults. However, to the degree that they are unable to recognise their best interests, express their own needs, protect themselves from harm, or make informed choices about the potential risks and benefits of research, children and young people are vulnerable members of society.

56. When involving children and young people in research you must protect their ethical, physical, mental and emotional rights and ensure that they are not exploited. It is important to assess carefully the potential benefits and harm to them, at all stages of any research.

57. You must always ensure that you have obtained consent before undertaking any research on children and young people. If they are not competent, independently, to consent to treatment then they should not participate in research without the consent of someone with parental responsibility. GMC guidance Consent: patients and doctors making decisions together gives advice on consent.

58. A full exposition of the issues concerning research that involve children is contained in ‘Guidelines for the ethical conduct of medical research involving children’.

Teaching, training and management

Teaching and supervision

59. All students should be introduced to the basic principles of good research practice as undergraduates. This should include the ethical importance of informed consent and the practical importance of related communication skills. It should also provide the basis for continuing, appropriate training at all stages of their education and professional development.

60. If you have special responsibilities for supervision of research or teaching you must develop and demonstrate the skills, attitudes and practices of a competent teacher because you will be a significant role model. You must make sure that students and junior colleagues who undertake research are properly supervised. Junior staff and research students who are being trained or supervised should always be given clear information about the roles and responsibilities of supervisors, teachers and mentors.

Keeping up to date

61. As a researcher you should keep your knowledge and skills up to date throughout your working life. You should take part regularly in educational activities that develop your competence and performance in research methods.
Managerial responsibilities for research

62. If you have management responsibility in an organisation undertaking research, or are leading a research team or a research project, the management tasks you undertake will have to meet the standards set by the GMC.13

63. If you have responsibility to act on concerns brought to your attention about the quality and integrity of the research including allegations of fraud or misconduct, you must ensure that systems are in place to deal with such concerns. Where such a concern is brought to your attention, you must take action promptly:

- taking account of participants' safety;
- establishing the facts as far as you are able, separating genuine concerns from those made mischievously or maliciously;
- protecting the person who has made the allegations and the person about whom the allegation is made, from harmful criticisms or actions.14

64. If you are leading a team, you must:

- ensure the research plans are clearly explained to the appropriate ethics committee(s), the health care organisations in which the research will take place, and other bodies with supervisory or regulatory responsibilities;
- ensure that all members of the team are competent and in a position to carry out their research responsibilities with integrity;
- take responsibility for ensuring that the team carries out the research in a manner which is safe, effective and efficient;
- do your best to make sure that the whole team understands the need to provide a polite, responsive and accessible service that respects the research participants' dignity and treats their information as confidential;
- ensure that research participants and colleagues understand your role and responsibilities in the team.

This booklet is not exhaustive. It cannot cover all the questions that may arise. You must therefore always be prepared to explain and justify your actions and decisions.

Other organisations issue guidance on issues of relevance to research and you will find details of where to obtain these at the end of this guidance.

GMC guidance and further information is available on our website http://www.gmc-uk.org. To request publications please contact our publications department: tel 0161 923 6315, or email publications@gmc-uk.org.

Notes

1 See Research Ethics Committees web site http://www.corec.org.uk

2 'A clinical trial with a medicinal product must receive authorisation for the supply of the product under Section 31 of the Medicines Act 1968 unless it is subject to an exemption.
Applications are made to the Medicines Control Agency (MCA). The authorisation is subject to certain conditions including the requirement to report adverse reactions to the product to the MCA.

3 Department of Health Research Governance Framework for Health and Social Care, March 01.

4, 6 In England and Wales

5 See our website for further guidance on Orders under the Health and Social Care Act 2001

7 See GMC website

8, 9 In Scotland you must take account of the terms of the Adults with Incapacity Act 2000

10 Guidelines for the ethical conduct of medical research involving children, Royal College of Paediatrics and Child Health: Ethics Advisory Committee in Archives of Disease in Childhood, February 2000, Vol 82, No 2, p 177-182

11 General Medical Council guidance The doctor as teacher is of relevance to all doctors.

12 Details of organisations providing continuous professional development (CPD) from your employer and/or professional association.

13 Management in Health Care: The Role of Doctors (134kb, pdf)

14 Doctors should be aware of the terms of the Public Interest Disclosure Act 1998.

Organisations with guidance on research and some key legislation

Organisations


Health Professions Council Park House, 184 Kennington Park Road, London, SE11 4BU: http://www.hpc-uk.org/index.asp
Departments of Health


Department of Health and Social Services Northern Ireland, Dundonald House, Upper Newtownards Road, Belfast BT4 3SF: http://www.dhsspsni.gov.uk.

National Assembly for Wales, Cardiff Bay, Cardiff CF99 1NA: http://www.wales.gov.uk.

Scottish Executive Health Department, St Andrew's House, Regent Road, Edinburgh EH1 3DG: http://www.sehd.scot.nhs.uk.


Medicines Control Agency, Market Place, 1 Nine Elms Place, London SW8 5NQ: http://www.mhra.gov.uk.


Royal College of General Practitioners, 14 Princes Gate London SW7 1PU: http://www.rcgp.org.uk.

Royal College of Paediatrics and Child Health. 50 Hallam Street London, W1N 6DE: http://www.rcpch.ac.uk.

Royal College of Pathologists, 2 Carlton House Terrace, London SW1Y 5AF: http://www.rcpath.org.uk.

Royal College of Physicians of Edinburgh, 9 Queen Street, Edinburgh, EH2 1JQ: http://www.rcpe.ac.uk.
Legislation


Anatomy Act 1984 and Anatomy Regulations 1988

Coroners Act 1988

Data Protection Act 1998

Health & Social Care Act 2001

Human Fertilisation and Embryology Act 1990

Human Tissue Act 1961

Human Rights Act 1998

Medicines Act 1968

Misuse of Drugs Act 1971

Mental Health Act 1983

Mental Health Act 1983 Revised Code of Practice

Public Interest Disclosure Act 1998

Northern Ireland

N Ireland Mental Health (N Ireland) Order 1986

Code of Practice Mental Health (N Ireland) Order 1986

Scotland

Adults with Incapacity (Scotland) Act 2000
Mental Health

(Public Safety and Appeals) (Scotland) Act 1999