Supplementary guidance

General Medical Council

Regulating doctors
Ensuring good medical practice

Good practice in research and *Consent to research*

The supplementary guidance *Good practice in research* and *Consent to research* set out the good practice principles that doctors are expected to understand and follow if they are involved in research. They provide more detailed guidance on how the principles in *Good Medical Practice* and in *Consent: patients and doctors making decisions together* apply in the context of research.

This document brings together all of the GMC's advice to doctors involved in research. This includes the full text of *Good practice in research* and *Consent to research* and extracts from:

Confidentiality on research and other secondary uses of data; and *0-18 years: guidance for all doctors* on involving children or young people in research. You can view an online version of the research guidance documents at **www.gmc-uk.org/guidance/research_guidance**

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Good practice in research

About this guidance

In our core guidance, *Good Medical Practice,*[1] we advise doctors who are involved in research that:

- You must help to resolve uncertainties about the effects of treatments. (Paragraph 14f)
- Research involving people directly or indirectly is vital in improving care and reducing uncertainty for patients now and in the future, and improving the health of the population as a whole. (Paragraph 70)
- If you are involved in designing, organising or carrying out research, you must put the protection of participants' interests first, act with honesty and integrity and follow the appropriate national research governance guidelines. (Paragraph 71)

This supplementary guidance is intended to provide more detailed advice about how to comply with these principles. It should be read in conjunction with our other guidance, in particular:

- *Consent to research*, which explains how the principles in *Consent: patients and doctors making decisions together*[2] apply to research,
- *Confidentiality,*[3] which gives guidance on research and other secondary uses of data, and
- *0-18 years: guidance for all doctors,* which gives additional advice on research involving children or young people.

Together, these guidance documents set out the GMC's advice to doctors involved in research. You must use your judgement in applying the principles in the guidance to the types of research you undertake, and to the situations you face in practice as a doctor, whether or not you hold a licence to practise. Serious or persistent failure to follow the guidance will put your registration at risk.

Scope of the guidance

1 Research in this guidance refers to an attempt to derive generalisable new knowledge. Research aims to find out what is best practice by addressing clearly defined questions with systematic and rigorous methods. It includes studies that aim to generate hypotheses as well as those that aim to test them.

2 This guidance covers research with people, as well as research involving human tissue and records-based research that does not involve people directly.

3 It also applies to clinical trials, which cover a broad range of different types of research involving people.[4] For example, they can test medicines or vaccines, treatments, surgical procedures, devices, or health prevention or care. A clinical trial of investigational medicinal products is a particular type of trial that is governed by legislation.[5] The key elements of the law for conducting a clinical trial of investigational medicinal products in the UK are set out in annex B.

4 This guidance does not apply to clinical audit or service evaluation projects, which aim to measure standards of care.[6] Nor does it cover innovative treatments designed to benefit individual patients. These activities are covered by the standards and principles set out in *Consent: patients and doctors making decisions together* and *Confidentiality*.

Principles of good research practice

5 To protect participants and maintain public confidence in research, it is important that all research is conducted lawfully, with honesty and integrity, and in accordance with good practice.

This guidance sets out principles of good research practice, which you must follow if you are involved in research.

Law and governance

6 The law and governance arrangements that apply to research are complex and vary depending on the type of research, the participants involved, how it is funded and where in the UK it is undertaken. You must comply with the law, governance arrangements and codes of practice that apply to the research you are undertaking. The legal annexes to this guidance give more detail and links to further information about the relevant legal and governance framework for research (see annex A) and the key elements of the legislation that governs clinical trials of investigational medicinal products in the UK (see annex B).

Good research design and practice

7 You must make sure that research is based on a properly developed protocol that has been approved by a research ethics committee.[7] It must be prepared according to good practice guidance given by government and other research and professional bodies.

8 You must make sure that the safety, dignity and wellbeing of participants take precedence over the development of treatments and the furthering of knowledge.[8]

9 You must make sure that foreseeable risks to participants are kept as low as possible. In addition, you must be satisfied that:

- the anticipated benefits to participants outweigh the foreseeable risks, or
- the foreseeable risks to participants are minimal if the research only has the potential to benefit others more generally.

10 You must make sure that decisions at all stages of research, especially for recruitment, are free from discrimination[9] and respect participants' equality and diversity. You should take all reasonable steps to make sure that people eligible to participate in a project are given equal access to take part and the opportunity to benefit from the research. Where appropriate, you should use patient and public involvement groups at all stages of the project to help make sure that the research is well designed and conducted.

11 You should make sure that details of a research project are registered on an eligible, publicly available database that is kept updated, where such a database exists.

12 You should be satisfied that appropriate monitoring systems are in place to make sure research is being carried out in accordance with the law and good practice.

13 You must keep your knowledge and skills up to date. If you lead a research team, you must make sure that all members of the team have the necessary skills, experience, training and support to carry out their research responsibilities as effectively as possible.

14 You should make sure that commercial and other interests do not stop or adversely affect the completion of research. If you are concerned about this you should follow the guidance on raising your concerns in paragraph 19.

Protecting participants from harm

15 You must stop research where the results indicate that participants are at risk of significant harm or, in research involving treatment required by a patient, where no benefit can be expected.

16 You must report adverse findings as soon as possible to the affected participants, to those responsible for their medical care, to the research ethics committee, and to the research sponsor[10] or primary funder where relevant. You must make sure that bodies responsible for protecting the public, for example, the Medicines and Healthcare products Regulatory Agency, are informed.[11]

17 You should make sure that participants are not encouraged to volunteer more frequently than is advisable or against their best interests. You should make sure that nobody takes part repeatedly in research projects if it might lead to a risk of significant harm to them. You should make sure that any necessary safeguards are in place to protect anybody who may be vulnerable to pressure to take part in research. You must follow our guidance in paragraphs 21-22 of *Consent to research* on involving vulnerable adults in research.

18 If a participant is involved in investigations that may contribute to a cumulative long-term risk of harm, for example, radiation from X-rays or radioactive substances, you must consider any previous exposure to the risk and make sure that a record is kept about their participation.[12]

19 If you have good reason to believe that participants are at risk of significant harm by taking part in research or by the behaviour of anyone conducting research, you must report your concerns to an appropriate person in your employing or contracting body. If you remain concerned you should inform the research ethics committee and the research sponsor or primary funder. You should follow the

guidance in *Raising concerns about patient safety*[13] if you are not sure when or how to raise concerns.

20 If you are responsible for acting on concerns raised by colleagues, you must make sure that reporting procedures are in place and that staff are aware of them. If a concern is brought to your attention you must take appropriate action promptly and professionally.[14]

Honesty and integrity

21 You must conduct research honestly. If you are concerned about the quality or integrity of the research, including allegations of fraud or misconduct, you must follow the guidance in paragraph 19 on raising concerns. You must report evidence of financial or scientific fraud, or other breaches of this guidance, to an appropriate person in your employing or contracting body, and where appropriate to the GMC or other statutory regulatory bodies.

22 You must be open and honest with participants and members of the research team, including non-medical staff, when sharing information about a research project. You must answer questions honestly and as fully as possible.

23 You must make clear, accurate and legible records of research results, as soon as possible after the data are collected. You must keep records for the appropriate period[15] to allow adequate time for review, further research and audit, or to help resolve any concerns about the data or research project.

24 You must report research results accurately, objectively, promptly and in a way that can be clearly understood.[16] You must make sure that research reports are properly attributed and do not contain false or misleading data. Whenever possible, you should publish research results, including adverse findings, through peer-reviewed journals.[17]

25 You should make research findings available to those who might benefit. You should make reasonable efforts to inform participants of the outcome of the research, or make the information publicly available if it is not practical to inform participants directly.

Avoiding conflicts of interest

26 You must be open and honest in all financial and commercial matters relating to your research and its funding.

27 You must not allow your judgement about a research project to be influenced, or be seen to be influenced, at any stage, by financial, personal, political or other external interests. You must identify any actual or potential conflicts of interest that arise, and declare them as soon as possible to the research ethics committee, other appropriate bodies, and the participants, in line with the policy of your employing or contracting body.

Consent to research

28 You must get consent from participants before involving them in any research project. You must have other valid authority before involving in research adults who lack capacity, or children or young people who cannot consent for themselves.

29 You must make sure that people are informed of, and that you respect, their right to decline to take part in research and to withdraw from the research project at any time, with an assurance that this will not adversely affect their relationship with those providing care, or the care they receive.

30 When seeking consent for research, you must follow the guidance in *Consent to research* and, where relevant, *Consent: patients and doctors making decisions together*.

Respecting confidentiality

31 You must respect participants' right to confidentiality, and make sure that any data collected as part of a research project are stored securely and in accordance with data protection and other requirements.

32 You must follow the guidance in *Confidentiality*, in particular the guidance in paragraphs 40-50 on research and other secondary uses, if you undertake records-based research that does not involve people directly.

In our *Confidentiality* guidance, we advise that:

40 Research, epidemiology, public health surveillance, health service planning and education and training are among the important secondary uses made of patient information. Each of these uses can serve important public interests.

41 For many secondary uses, it will be sufficient and practicable to disclose only anonymised or coded information. When identifiable information is needed, or it is not practicable to remove identifiable information, it will often be perfectly practicable to get patients' express consent.

42 You may disclose identifiable information without consent if it is required by law, if it is approved under section 251 of the *NHS Act 2006*, or if it can be justified in the public interest and it is either:

(a) necessary to use identifiable information, or
(b) not practicable to anonymise or code the information

and, in either case, not practicable to seek consent (or efforts to seek consent have been unsuccessful).

43 In considering whether it is practicable to seek consent you should take account of:

(a) the age of records and the likely traceability of patients
(b) the number of records, and
(c) the possibility of introducing bias because of a low response rate or because particular groups of patients refuse, or do not respond to, requests to use their information.

44 When considering whether the public interest in disclosures for secondary uses outweighs patients' and the public interest in keeping the information confidential, you must consider:

(a) the nature of the information to be disclosed
(b) what use will be made of the information
(c) how many people will have access to the information
(d) the confidentiality and security arrangements in place to protect the information from further disclosure
(e) the advice of a Caldicott Guardian or similar expert adviser, who is not directly connected with the use for which disclosure is being considered, and
(f) the potential for distress or harm to patients.

45 When considering applications for support under section 251 of the *NHS Act 2006* in England and Wales, the National Information Governance Board considers:

(a) the feasibility of doing the research or other activity with patients' consent or by using anonymised or coded information, and
(b) whether the use of identifiable information would benefit patients or the public sufficiently to outweigh patients' right to privacy.

46 The Privacy Advisory Committee in Northern Ireland can advise on some of the same considerations; but it has no statutory powers and so cannot give lawful authority to disclosures of identifiable information without consent. In the event of a complaint or challenge, its advice on best practice might play an important part in any assessment of the propriety of a disclosure.

47 The Privacy Advisory Committee in Scotland performs a different role, and doctors there should seek the advice of Caldicott Guardians, defence organisations or professional bodies if they are unsure about whether disclosures of identifiable information for secondary uses can be justified in the public interest.

48 It might not be practicable for the healthcare team, or those who usually support them, to anonymise or code information or to seek patients' express consent:

(a) for the disclosure of identifiable information for important secondary uses, or
(b) so that suitable patients can be recruited to clinical trials or other approved research projects.

49 If that is the case:

(a) identifiable information may be sent to a 'safe haven', where they exist and have the capabilities and are otherwise suitable to process the information (including anonymising or coding it) and to manage the disclosure of information for secondary uses or, if that is not practicable
(b) the task of anonymising or coding the information or seeking patients' consent to disclosure can be delegated to someone incorporated into the healthcare team on a temporary basis and bound by legal and contractual obligations of confidentiality.

50. You should only disclose identifiable information for research if that research is approved by a Research ethics committee. You should alert Research ethics committees to disclosures of identifiable information without consent when applying for approval for research projects.

Endnotes

1 *Good Medical Practice*. See **www.gmc-uk.org/guidance/good_medical_practice.asp**

2 *Consent: patients and doctors making decisions together.* See **www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_index.asp**

3 *Confidentiality*. See **www.gmc-uk.org/guidance/ethical_guidance/confidentiality_40_50_research_and_secondary_issues.asp**

4 The World Health Organization defines a clinical trial as any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials may also be referred to as interventional trials. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices,

behavioural treatments, process-of-care changes, preventive care, etc. This definition includes phase I to phase IV trials.

5 Under the *Medicines for Human Use (Clinical Trials) Regulations 2004* a clinical trial means 'any investigation in human subjects, other than a non-interventional trial, intended –

(a) to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products,
(b) to identify any adverse reactions to one or more such products, or
(c) to study absorption, distribution, metabolism and excretion of one or more such products, with the object of ascertaining the safety or efficacy of those products'.

An investigational medicinal product 'means a pharmaceutical form of an active substance or placebo being tested, or to be tested, or used, or to be used, as a reference in a clinical trial, and includes a medicinal product which has a marketing authorization but is, for the purposes of the trial –

(a) used or assembled (formulated or packaged) in a way different from the form of the product authorised under the authorization,
(b) used for an indication not included in the summary of product characteristics under the authorization for that product, or
(c) used to gain further information about the form of that product as authorised under the authorization'.

The Medicines and Healthcare products Regulatory Agency (MHRA) provide guidance to help work out whether a study is a trial of investigational medicinal products. See **www.mhra.gov.uk/home/groups/l-unit1/documents/websiteresources/con009394.pdf**

6 The National Research Ethics Service provides definitions of research, clinical audit, service evaluation and surveillance. See **www.nres.npsa.nhs.uk/applications/guidance/**

7 Research ethics committees (RECs) have a responsibility to safeguard the rights, safety, dignity and wellbeing of people participating in research. They review applications for research and give opinions about the proposed participant involvement and whether the research is ethical. Guidance on whether research requires ethical review under either the law or the policy of the UK health departments can be found on the National Research Ethics Service website. See **www.nres.npsa.nhs.uk/applications/guidance/**

8 The Declaration of Helsinki states that 'The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best current proven intervention, except in the following circumstance. The use of placebo, or no treatment, is acceptable in studies where no current proven intervention exists or where for compelling and scientifically sound methodological reasons the use of placebo is necessary to determine the efficacy or safety of an intervention and the patients who receive the placebo or no treatment will not be subject to any risk of serious or irreversible harm. Extreme care must be taken to avoid abuse of this option.'(World Medical Association Declaration of Helsinki, 2008). See **www.wma.net/en/30publications/10policies/b3/index.html**

9 Restricting research participants to subgroups of the population that may be defined, for example, by age, gender, ethnicity or sexual orientation, for legitimate methodological reasons does not constitute discrimination.

10 A sponsor is the person, individual or group that takes responsibility for the initiation, management and financing (or arranging the financing) of the research. All research undertaken in the NHS must have a sponsor. You should refer to the *Medicines for Human Use (Clinical Trials) Regulations 2004* for a full definition of a sponsor and its responsibilities in clinical trials of investigational medicinal products.

11 See **www.mhra.gov.uk/index.htm**

12 Further advice is provided in the publication *Notes for Guidance on the Clinical Administration of Radiopharmaceuticals and Use of Sealed Radioactive Sources* (Administration of Radioactive Substances Advisory Committee, 2006). See **www.arsac.org.uk/notes_for_guidance/index.htm**

13 *Raising concerns about patient safety.* See **www.gmc-uk.org/guidance/ethical_guidance/raising_concerns.asp**

14 Further advice on responding to incidents and complaints is set out in paragraphs 44-45 of *Management for doctors*.
See **www.gmc-uk.org/guidance/ethical_guidance/management_for_doctors.asp**

15 *Personal Information in Medical Research* (Medical Research Council, 2000) provides further advice on how long research records should be kept. The *NHS Code of Practice: Records Management* (Department of Health, 2006); *Records Management: NHS Code of Practice* (Scotland) (Scottish Government, 2008); *Welsh Health Circular (2000) 71: For The Record* (National Assembly for

Wales); and *Good Management*, *Good Records* (Department of Health, Social Services and Public Safety, Northern Ireland, 2005) all include schedules of the minimum periods for which research records should be kept.

16 The EQUATOR Network website provides advice on good practice in reporting health research. See **www.equator-network.org/**

17 Further information on publication and authorship is provided in section 3.15 of the *Code of Practice for Research: Promoting good practice and preventing misconduct* (UK Research Integrity Office, 2009). See **www.ukrio.org/resources/UKRIO%20Code%20of%20Practice%20for%20Research.pdf**

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Consent to research

About this guidance

Our guidance *Consent: patients and doctors making decisions together*[1] sets out the principles of good practice in making decisions in partnership with patients. That guidance focuses on decision making in the context of investigations and treatment, but the principles apply more widely, including to decisions on taking part in research. It gives advice on sharing information, discussing side effects, complications and other risks, and making and recording decisions. When relevant, you must follow the principles it sets out when seeking people's consent to take part in research.

This supplementary guidance is intended to explain how good practice principles in making decisions and seeking consent apply to research. It also provides advice on involving in research children or young people, vulnerable people, and people who lack capacity to consent.

Annex B explains the key elements of the legislation for seeking people's consent to take part in clinical trials of investigational medicinal products.[2]

You should read this guidance in conjunction with our other guidance, in particular:

- *Good practice in research*, which sets out the principles on which good practice in research is founded,
- *Confidentiality*,[3] which gives guidance on research and other secondary uses of data, and
- *0-18 years: guidance for all doctors,* which gives additional advice on research involving children or young people.

Together, these guidance documents set out the GMC's advice to doctors involved in research. You must use your judgement in applying the principles in the guidance to the types of research you undertake, and to the situations you face in practice as a doctor, whether or not you hold a licence to practise. Serious or persistent failure to follow the guidance will put your registration at risk.

Seeking consent

Valid consent

1 Seeking consent is fundamental in research involving people. Participants' consent is legally valid and professionally acceptable only if they have the capacity to decide whether to take part in the research, have been properly informed, and have agreed to participate without pressure or coercion.

2 When conducting research involving people who cannot consent for themselves, you must follow the guidance that applies, such as the advice on research involving children or young people in paragraphs 14-20 and on adults who lack capacity in paragraphs 23-35.

Right to withdraw from research

3 You must make sure that people are informed of, and that you respect, their right to decline to take part in research and to withdraw from the research project at any time, with an assurance that this will not adversely affect their relationship with those providing care or the care they receive. You should tell people if the treatment options available to them might be affected by a decision to withdraw from a research project.

Sharing information

4 You must give people the information they want or need in order to decide whether to take part in research. How much information you share with them will depend on their individual circumstances. You must not make assumptions about the

information a person might want or need, or their knowledge and understanding of the proposed research project.

5 In most cases, the information people will need to decide whether to take part in research will be included in the participant information sheet. The National Research Ethics Service gives advice on the design of information sheets and consent forms, and the key points they should cover. You should follow that advice if you are developing information sheets or consent forms.[4]

6 You should give people any further information they ask for. This might include a copy of the protocol approved by a research ethics committee (subject to considerations of confidentiality, commercial privilege or the possible undermining of the purpose of the study). You should make sure people have the details of an individual or organisation they can contact to discuss the research project and get further information.

Giving information in a way that people can understand

7 You must make sure that people are given information in a way that they can understand. You should check that people understand the terms that you use and any explanation given about the proposed research method. If necessary, you should support your discussions with simple and accurate written material or visual or other aids.

8 You must make sure, whenever practical, that arrangements are made to meet people's language, communication and other support needs. It is important to make sure that people who require additional assistance are not excluded from research and from the benefits that research can offer them and the wider groups to which they belong.

Responsibility for seeking consent

9 If you are responsible for seeking consent, you must understand the research project, including what the project will involve and any anticipated benefits and foreseeable risks.

10 If you delegate the responsibility to someone else, you must make sure they have sufficient understanding of the research project, and the appropriate skills and competence to seek consent.

Recording consent

11 You should record the key elements of your discussion with people about their decision to take part in research. If practical, you should ask them, or someone with valid authority, to give written consent. It is a legal requirement to get written consent from participants in clinical trials of investigational medicinal products.[5]

Sharing information with others involved in care

12 With the participant's consent, you should usually inform their GP and other clinicians responsible for their care about their involvement in a research project, and you should provide the doctors with any other information necessary for the participant's continuing care. You should follow this advice regardless of whether the participant is a patient or a healthy volunteer.

13 If a participant objects to information being shared in this way, you should explain to them the potential consequences of not sharing information. If the participant continues to object, you must respect their wishes, unless sharing the information is justified in the public interest.[6]

Areas requiring special consideration

Research involving children or young people

14 When considering involving children or young people in research, you must follow the advice in *0-18 years: guidance for all doctors*.[7] It gives advice on the circumstances in which children or young people can be involved in research, effective communication with children and young people, and assessing capacity to consent. It also explains the different legal requirements across the UK for 16 and 17-year olds who lack capacity to consent.

In *0-18 years: guidance for all doctors*, we give specific advice about research involving children or young people. In this section we advise that:

36 Research involving children and young people can benefit all children; but they may be vulnerable because they cannot always recognise their best interests, express their needs or defend their rights.

37 Children or young people should be involved in research only when research on adults cannot provide the same benefits. They can be involved in research that has either:

(a) potential benefits for children or young people generally, as long as the research does not go against their best interests or involves only minimal or low risk of harm (this would be research that involves, for example, asking questions or taking blood samples, the assessment of the risk depending on the view of the child or young person), or

(b) potential therapeutic benefits for them that outweigh any foreseeable risks, which should be kept as low as possible.

38 Children and young people should not usually be involved in research if they object or appear to object in either words or actions, even if their parents consent. If they are able to consent for themselves, you should still consider involving their parents, depending on the nature of the research.

39 You must not put pressure on children, young people or their parents to consent to research in the expectation of therapeutic, financial or any other benefit.

40 Before involving children or young people in research, you should seek advice and get the necessary approval from a relevant research ethics committee, the Medical Research Council or a medical royal college.

15 There are particular considerations in relation to seeking and acting on consent for children or young people to participate in research. As part of seeking approval for the project from a research ethics committee, you must clearly explain the arrangements for getting consent and seek advice if necessary.

16 Before involving a child or young person in research you must get consent from a parent,[8] but you should get consent from both parents, if possible, particularly if the research involves more than low or minimal risk of harm. If a parent is under 16 years of age, you must get consent from them if they have the capacity to make a decision about whether their child should take part in the research project. If a child or young person is able to consent for themselves, you should still consider involving their parents, depending on the nature of the research.

17 You should aim to reach a consensus with parents about a child or young person's participation in research. If disagreements arise it is usually possible to resolve them informally, and you should follow the advice in paragraphs 77-78 in *Consent: patients and doctors making decisions together*. If disagreements cannot be resolved informally, you should not involve the child or young person in research, unless the treatment can be accessed only as part of a research project and you assess that it is in their best interests. In these circumstances, if the decision about entering the child or young person in research has significant consequences for the child or young person, you should seek legal advice about whether you should apply to the appropriate court for an independent ruling.

18 You should be familiar with the guidance on involving children or young people in research published by other relevant organisations,[9] for example, the Medical Research Council, the Royal College of Paediatrics and Child Health, the Royal College of Physicians of London, and the British Medical Association. Annex B contains specific advice on some of the legal requirements for involving children or young people under 16 in clinical trials of investigational medicinal products.

Emergency research

19 Circumstances may arise where involvement in research has the potential to benefit a child or young person who lacks capacity, but an urgent decision about the child's involvement needs to be made before it is possible to get consent from a parent. This may arise because a parent cannot reasonably be contacted, or they do not have capacity to consent because of their own condition or distress. In such cases you can involve a child or young person in research if you have the approval of a research ethics committee for such recruitment. You must seek the consent of a parent as soon as possible to continue involving them in the project.

20 There are specific legal requirements that relate to involving children or young people under 16 in emergency clinical trials of investigational medicinal products. Annex B contains further guidance on the legal requirements in these circumstances.

Research involving vulnerable adults

21 Some adults with capacity may be vulnerable to pressure to take part in research. You should be aware that their health or social circumstances might make them vulnerable to pressure from others. Vulnerable adults may be, for example, living in care homes or other institutions, or have learning difficulties or mental illness. In these circumstances, it is particularly important that you check whether they need any additional support to understand information or to make a decision.[10] You must make sure that they know they have the right to decline to participate in research, and that they are able to decline if they want to. The Royal College of Physicians of London provides further guidance on involving vulnerable groups in research.[11]

22 You should raise concerns with a senior colleague, or your employing or contracting organisation, if systems are not in place to provide the additional support that vulnerable adults may need to make a decision about taking part in research. If you are not sure when or how to raise concerns, you should follow the guidance in *Raising concerns about patient safety*.[12]

Research involving adults without capacity

23 This section gives guidance about specific issues in research involving adults who lack capacity. It sets out the key elements of the law that governs the involvement of people over 16 who lack capacity to consent. Annex A contains a summary of the law in this area, and annex B explains the key elements of the legislation that governs clinical trials of investigational medicinal products in the UK.

24 You must assess an adult's capacity to make a particular decision at the time it needs to be made. You must follow the guidance in part 3 of *Consent: patients and doctors making decisions together*,[13] which gives advice on maximising a person's ability to make decisions, and on assessing capacity.

When adults without capacity might be involved in research

25 You must only undertake research involving an adult who lacks capacity if it is related to their incapacity or its treatment. You must not involve in research adults who lack capacity if the same or similar research could be undertaken by involving only people with capacity.

26 You should only involve in research adults who lack capacity, including clinical trials of investigational medicinal products, if the research is expected to provide a benefit to them that outweighs the risks. Research, not including clinical trials of investigational medicinal products, may also involve adults who lack capacity if the research is not expected to provide a direct benefit to them but is expected to contribute to the understanding of their incapacity, leading to an indirect benefit to them or others with the same incapacity, and if the risks are minimal. This means that the person should not suffer harm or distress by taking part. In all research involving adults who lack capacity, you must make sure that the foreseeable risks are kept as low as possible.[14]

Seeking to involve adults without capacity in research

27 You should consider the views of people close to the adult who lacks capacity to consent before involving that person in a research project. They are often best placed to know the person's wishes about taking part in research. In clinical trials of investigational medicinal products, you must get consent from a legal representative.[15]

28 Under the *Mental Capacity Act 2005* (in England and Wales) you must consult a consultee[16] about whether the adult who lacks capacity should take part in the research, and what they think that person's wishes would be if they had capacity to decide for themselves. If the consultee considers that they probably would not wish to take part, you must not include them in the research. Under the *Adults with Incapacity (Scotland) Act 2000*, you must get consent from any guardian or welfare attorney who has power to consent to the adult's participation in research or, if there is no such guardian or welfare attorney, from the person's nearest relative.[17]

29 If you are seeking to involve an adult who has lost capacity to consent, for example, through onset or progress of a condition that has impaired their capacity, such as dementia, you should take all reasonable steps to find out whether they have previously indicated their wishes about participating in future research, including any refusal to participate. You must consider any evidence of the person's previously expressed preferences, such as an advance statement or decision.[18]

Right to withdraw from research

30 You must make sure that a participant's right to withdraw from research is respected. You should consider any sign of objection, distress or indication of refusal, whether or not it is spoken, as implied refusal. Under the *Mental Capacity Act 2005* (in England and Wales) you should usually withdraw the participant from the research if the consultee considers that they would wish to be withdrawn. In clinical trials of investigational medicinal products, the legal representative can withdraw the participant from the trial at any time.

Loss of capacity during a research project

31 Some people with capacity will consent to take part in research, but then may lose capacity before the end of the project. If you become aware that a participant has lost capacity, you should consider carefully the benefits and harm that could occur from their continued participation in the research, and you must follow the law that applies where you work.[19]

32 If you are seeking to involve a person in research who you believe may lose capacity during the course of the project, you should consider seeking their views about the circumstances in which they would wish to continue to participate. You should explain to them the steps that would be taken to decide whether they should continue to take part and how their wishes, if known, would be taken into account.

Research into treatment in emergencies

33 You may want to undertake urgent research into procedures or treatments used in emergencies when a person is unconscious or otherwise unable to make a decision. In an emergency situation it is not always possible to get consent to involve a person in research using the standard consent procedures.

34 The *Mental Capacity Act 2005* permits urgent research in emergencies to start when it is not practical to consult someone about involving a person who lacks capacity in research. In this situation you must either get agreement from a doctor not involved in the research, or follow a procedure approved by a research ethics committee. Similarly, you can start a clinical trial of investigational medicinal products when it needs to be undertaken urgently if you cannot get the consent of a legal representative, as long as a research ethics committee has given approval for such action. The *Adults with Incapacity (Scotland) Act 2000* provides for emergency clinical trials of investigational medicinal products but not for other types of emergency research. If this situation arises you should seek legal advice on how to proceed.

35 You must follow the law on continuing to involve in emergency research an adult who lacks capacity. You must get consent from the adult as soon as possible if they recover capacity.

Research involving human tissue

36 You must keep up to date with, and comply with, the laws and codes of practice that apply to the use in research of human organs, tissue and cells. The Human Tissue Authority (HTA) publishes a number of codes of practice,[20] including those on consent and research, which advise on the issues you should consider when seeking consent for the purpose of research.

37 In England, Wales and Northern Ireland, the *Human Tissue Act 2004* requires consent[21] to be obtained before the storage and use of a living person's organs, tissue or cells for the purpose of research in connection with disorders in, or the functioning of, the human body. In a number of specific circumstances, there are exceptions to the consent requirements; for example, a living person's organs, tissue or cells may be stored and used without consent if the researcher is unable to identify the person it has come from, and if it is used for a specific research project that has been approved by a research ethics committee. The *Human Tissue Act 2004* also requires consent to be obtained for the removal, storage and use of a deceased person's organs, tissue and cells for the purpose of research in connection with disorders in, or the functioning of, the human body. Regulations[22] made under the *Human Tissue Act 2004* permit the use and storage of organs, tissue or cells from adults who lack capacity for research under certain circumstances.

38 The *Human Tissue (Scotland) Act 2006* requires authorisation to be obtained before the storage and use of a deceased person's organs, tissue or cells for the purposes of research.[23] The Act does not cover the storage and use of tissue from living people for the purposes of research.

39 The *Medicines for Human Use (Clinical Trials) Regulations 2004* apply to the use of tissue in clinical trials of investigational medicinal products.

Endnotes

1 *Consent: patients and doctors making decisions together.* See **www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_index.asp**

2 Under the *Medicines for Human Use (Clinical Trials)* Regulations 2004 a clinical trial means 'any investigation in human subjects, other than a non-interventional trial, intended –

(a) to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products,
(b) to identify any adverse reactions to one or more such products, or
(c) to study absorption, distribution, metabolism and excretion of one or more such products, with the object of ascertaining the safety or efficacy of those products'.

An investigational medicinal product 'means a pharmaceutical form of an active substance or placebo being tested, or to be tested, or used, or to be used, as a reference in a clinical trial, and includes a medicinal product which has a marketing authorization but is, for the purposes of the trial –

(a) used or assembled (formulated or packaged) in a way different from the form of the product authorised under the authorization,
(b) used for an indication not included in the summary of product characteristics under the authorization for that product, or
(c) used to gain further information about the form of that product as authorised under the authorization'.

3 *Confidentiality*. See **www.gmc-uk.org/guidance ethical_guidance/confidentiality_40_50_research_and_secondary_issues.asp**

4 *Information & consent forms. Guidance for researchers and reviewers* (National Research Ethics Service, 2009). See **www.nres.npsa.nhs.uk/applications/guidance/**
Explaining research (National Research Ethics Service, 2008). See **www.nres.npsa.nhs.uk/EasySiteWeb/GatewayLink.aspx?alId=356**

5 In clinical trials of investigational medicinal products, consent is only valid if it is recorded

in writing. If the person is unable to give written consent, for example, if they have a disability which means that they cannot write, they can give consent orally in the presence of at least one witness and this must be recorded in writing.

6 Paragraphs 25-29 of *Confidentiality* provide further advice on sharing information with others involved in care. See **www.gmc-uk.org/guidance/ethical_guidance/confidentiality_40_50_research_and_secondary_issues.asp**

7 *0-18 years: guidance for all doctors.* See **http://www.gmc-uk.org/guidance/ethical_guidance/children_guidance_index.asp**

8 References to parent or parents in this guidance mean those with parental responsibility for the child. See appendix 2 of *0-18 years: guidance for all doctors* for an explanation of this term. You should also consider the views of others who are close to the child or young person but who do not have parental responsibility. See **www.gmc-uk.org/guidance/ethical_guidance/children_guidance_appendix_2.asp**

9 *Medical research involving children* (Medical Research Council, 2004). See **www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002430**

Guidelines for the ethical conduct of medical research involving children (Royal College of Paediatrics and Child Health: Ethics Advisory Committee, 2000). See **http://adc.bmj.com/content/82/2/177.full?ijkey=4c02338a134372bb98433e55aee27951cd3f67a5&keytype2=tf_ipsecsha**

Guidelines on the practice of ethics committees in medical research with human participants (Royal College of Physicians, 2007)

10 Paragraphs 18-21 of *Consent: patients and doctors making decisions together* provide guidance on sharing information. See **www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_sharing_information.asp**

11 *Guidelines on the practice of ethics committees in medical research with human participants* (Royal College of Physicians, 2007)

12 *Raising concerns about patient safety.* See **www.gmc-uk.org/guidance/ethical_guidance/raising_concerns.asp**

13 *Consent: patients and doctors making decisions together.* See **www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_part3_capacity_issues.asp**

14 For the legal requirements to involve an adult without capacity in research see the *Mental Capacity Act 2005* (section 31) and the *Mental Capacity Act 2005 Code of Practice* (chapter 11, paragraphs 11.9-11.19); *Adults with Incapacity (Scotland) Act 2000* (section 51); *Medicines for Human Use (Clinical Trials) Regulations* 2004 (schedule 1, part 5).

15 A legal representative under the *Medicines and Human Use (Clinical Trials) Regulations* 2004 means a person who is suitable to act as a legal representative for a minor (under 16) or an adult who lacks capacity for the purpose of the trial and is available and willing to do so. They must not be involved in the conduct of the trial. For trials involving adults who lack capacity in Scotland, a legal representative means any guardian or welfare attorney who has power to consent, or the adult's nearest relative. In all cases, if there is no such person, a doctor not connected with the conduct of the trial but who is responsible for the medical treatment of the minor or adult, or a person nominated by the relevant healthcare provider can be approached. You should refer to the regulations for a full description.

16 *Guidance on nominating a consultee for research involving adults who lack capacity to consent* (Department of Health, 2008). See **www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_083131**

17 *The Adults with Incapacity (Scotland) Act 2000 Part 5 Code of Practice: A short guidance to the Act* provides information about guardian and welfare attorneys. See **www.scotland.gov.uk/Publications/2008/03/25120154/1**

18 See the *Mental Capacity Act Code of Practice* (chapter 11, paragraph 11.30); *Adults with Incapacity (Scotland) Act 2000 Part 5 Code of Practice* (the general principles section); *Medicines for Human Use (Clinical Trials) Regulations 2004* (schedule 1, part 1, section 1(5)).

19 There are specific regulations under the *Mental Capacity Act 2005* for participants who gave consent before 31 March 2008 to take part in research that began before October 2007 but subsequently lost capacity to consent to continue to take part in the project.

Mental Capacity Act 2005 (Loss of Capacity during Research Project) (England) Regulations 2007

*Mental Capacity Act 2005 (*Loss of Capacity during Research Project) (Wales) Regulations 2007

There are no specific legal provisions under the *Adults with Incapacity (Scotland) Act 2000* relating to the loss of capacity during research in Scotland. In clinical trials of investigational medicinal products, consent from an adult to participate in a

trial remains valid after loss of capacity providing the trial is not significantly altered (*Medical Research Council ethics guide: medical research involving adults who cannot consent*, 2007).

20 *Human Tissue Authority – Codes of Practice.* See **www.hta.gov.uk/policiesandcodesofpractice/codesofpractice.cfm**

21 *The Human Tissue Authority's Code of Practice 9 – Research* advises that you can rely on generic consent but you must make sure consent is valid. If the intention is to store the tissue for an as yet unknown research purpose or as part of a tissue bank for research then this should be explained, setting out the types of research that may be involved, any wider implications and the circumstances under which the tissue will be disposed of. See **www.hta.gov.uk/policiesandcodesofpractice/codesofpractice.cfm**

22 *Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006.* See **www.opsi.gov.uk/SI/si2006/20061659.htm**

23 *Summary of legal requirements for research with human tissue in Scotland* (Medical Research Council, 2007). See **www.ukcrc-rgadvice.org/Documents/MRC_Human_Tissue_Summary_Scotland.pdf**