General Medical Council

Professional standards

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Good practice in research

Summary

Research saves lives and is vital to improving patient care and the health of the population. All health professionals can play a role in supporting research. This might involve:

- **raising patients' awareness of opportunities to take part**
- **recruiting people for clinical trials and other studies**
- **designing, organising, and carrying out research projects**
- **encouraging research activity and the use of research evidence.**

This guidance sets out the professional standards expected of you, whatever role you may play in supporting research. It will help you to make sure you work in line with the law and the UK research governance arrangements, as set out in the UK Policy Framework for Health and Social Care Research (the Policy Framework), where it applies to your work.

General Medical Council

Good practice in research

Professional standards: more detailed guidance

This guidance was published on 9 September 2024

This guidance will come into effect on 18 December 2024

You can find the latest version of all our professional standards at www.gmc-uk.org/guidance.

Contents

1. *Good medical practice* sets out the principles, values, and standards of care and professional behaviour expected of all medical professionals registered with us. *Good practice in research* builds on *Good medical practice* to provide more detail on our expectations of medical professionals involved in supporting or carrying out research.

2. The professional standards describe good practice, and not every departure from them will be considered serious. You must use your professional judgement to apply the standards to your day-to-day practice. If you do this, act in good faith and in the interests of patients, you will be able to explain and justify your decisions and actions. We say more about professional judgement, and how the professional standards relate to our fitness to practise processes, appraisal, and revalidation, at the beginning of *Good medical practice*.

Introduction

3. Research attempts to derive new knowledge which is generalisable and transferable, by exploring clearly defined questions using scientifically sound methods. Research within healthcare (which may include social care) focuses on:

    a. identifying the best means to prevent, diagnose, and treat conditions
    b. understanding the needs of and improving outcomes for patients
    c. delivering more efficient and effective services to meet the needs of the wider patient population.

4. This guidance relates to interventional research where a change in treatment, care, or other services is made for the purposes of the research, such as clinical trials. It also includes non-interventional projects, which do not involve any change in standard treatment, care, or other services, such as research using human tissue or health records. It includes studies that aim to generate hypotheses as well as those that aim to test them. A fuller description of activities that qualify as research is provided in the UK Policy Framework for Health and Social Care Research.[1]

5. Research does not include clinical audit or service evaluation projects that examine standards of care. Nor does it cover providing an innovative or experimental treatment or procedure solely to meet the specific needs of an individual patient. Decisions about

[1] The UK Policy Framework for Health and Social Care Research is statutory guidance issued by the NHS Health Research Authority in partnership with the four UK Health Departments.

providing innovative treatments or approaches are covered by our *Decision making and consent* guidance.[2]

6. This guidance is divided into two substantive sections:
    a. the role of all medical professionals in achieving the benefits of research (paragraphs 7–16)
    b. guidance for those designing, organising, or carrying out research in the UK (paragraphs 17–54).

All medical professionals

7. Research is vital in improving our understanding of health conditions, increasing the availability of options for effective prevention, treatment, and care, and improving outcomes for patients and the population. All medical professionals can play a role in achieving these benefits.[3]

8. You should consider opportunities to conduct or participate in research that may benefit current and/or future patients and help to improve the health of the population.

9. Whether you carry out, promote participation in, or promote the use of research, you must act with integrity and put the safety and interests of patients and participants first.

Promoting patient and public participation in research

10. There are many ways in which patients and the public can take part in healthcare research, whether as study participants, collaborators in study design and delivery, or advisers on research priorities—drawing on their lived experience of health conditions. However, some people are not aware of these opportunities, or may have a poor understanding of what would be involved. Some groups, such as women, children and young people, older people, ethnic minorities, and people with disabilities, are less well-represented in clinical studies and other research activity. This can affect the quality and relevance of research outputs.

11. To support more people to access and contribute to research, you should:

[2] The Health Research Authority's online decision tool can help people decide whether or not their study is research as defined by the UK Policy Framework for Health and Social Care Research.

[3] In England, under the Health and Care Act 2022 Integrated Care Boards (ICBs) have a statutory duty to facilitate or otherwise promote a) research on matters relevant to the health service, and b) the use in the health service of evidence obtained from research. Health professionals have a role to play in supporting ICBs to deliver their statutory duty.

a. tell patients if you're aware of opportunities for them to participate in research activities that may be relevant to their condition or of particular interest to them
b. signpost patients to research teams who can provide further information about a specific study
c. signpost patients who express a general interest in research to information on how they can get involved (see Annex B for examples)
d. avoid making assumptions about who may be interested in taking part, or eligible to be involved
e. encourage people from under-represented groups to consider getting involved.

12. When explaining opportunities that may exist for taking part in research, you must:

a. make clear that participation is voluntary and that deciding to take part (or not) will not affect someone's relationship with their usual doctor and healthcare team
b. make clear that research is governed by legal and ethical requirements
c. be open and honest about any interests you have in research that may affect (or could be seen to affect) your advice or recommendations.

Creating research supportive workplaces

13. When healthcare professionals engage with research opportunities as part of their clinical work, there are clear benefits to individual patients, overall patient care, the work of healthcare teams, care organisations, and professionals themselves.[4]

14. You should be willing to offer support to the wider team, to help create a research supportive workplace environment. Depending on your role this might include:

a. sharing information with colleagues about research opportunities
b. identifying possible areas for study and local research priorities
c. supporting and encouraging those you manage or supervise to take part in research
d. supporting the design, funding, or delivery of research
e. ensuring that colleagues from under-represented groups have fair access to research opportunities.

15. If you're aware of research findings that could improve clinical practice or service delivery, you should use appropriate opportunities to share this evidence with colleagues.

16. You must make sure the information you communicate to colleagues about research reports and findings is accurate and gives a balanced view of the evidence.

[4] General Medical Council: 'Normalising research – Promoting research for all doctors'

Designing, organising, or carrying out research

17. When designing, organising, or carrying out research in the UK, you must:

    a. be competent to carry out your tasks
    b. keep up to date with and take account of relevant national laws, statutory codes, and regulations
    c. meet the statutory requirements in the UK Policy Framework for Health and Social Care Research (the Policy Framework)
    d. follow the principles of good research practice set out in paragraphs 18–54, so far as they're applicable or relevant to the research involved.

Research governance

18. You must work in line with the Policy Framework established jointly by the Health Research Authority; the health departments in Scotland, Wales, and Northern Ireland; and other national oversight bodies. The Framework includes a description of all the roles that must be in place to support research projects and programmes, and their specific responsibilities.[5] Many of these responsibilities will be undertaken or supported by healthcare organisations (such as NHS trusts), or by Higher Education Institutions.

19. The Policy Framework sets out principles of good practice to make sure that research participants are safe; their rights are respected; and the public can have confidence in research integrity and outcomes.[6] The principles are consistent with our professional standards.

Design of research projects

20. Research projects are typically scrutinised by funding agencies (typically using external peer review), the Health Research Authority (HRA), the Medicines and Healthcare products Regulatory Agency (MHRA) where appropriate, and by research sponsors (usually the NHS trust or similar organisation). The design of research projects should therefore follow the principles of these organisations.

21. Proposed research must be scientifically sound, ethical, legal, and seek to maximise the safety of those involved. Good research design ensures a project meets standards for

[5] Roles and responsibilities of individuals and organisations can be found in Section 9 of the UK Policy Framework.

[6] See Section 8 of the UK Policy Framework for the Principles that apply to health and social care research.

integrity, quality, and transparency, and, where possible and relevant, includes patient and public involvement.

22. You must make sure the research design ensures the safety, dignity, and wellbeing of participants.

23. You must make sure that foreseeable risks of research to participants are kept as low as possible. You must be satisfied as far as you can that the anticipated benefits of the research outweigh the foreseeable risks to participants.

24. When you're planning research, you must make sure that the proposals or protocols are properly developed, in line with guidance on good practice from the HRA and other approval bodies.[7]

25. Before you submit a proposal or protocol for approval, you should consider whether it pays sufficient attention to:

    a. including people from groups that are less well-represented in research
    b. ensuring that people who share protected characteristics have equal access to participate and equal opportunity to benefit from the proposed research
    c. the perspective of people with lived experience of any condition to be studied.

26. Before you start your research the proposal or protocol must have received approval by a research ethics committee, or other relevant approval body[8] – where their review is expected or required.

Conduct of research projects

27. If you have a designated role in overseeing, sponsoring, or leading research projects, (as set out in the UK Policy Framework), you must take steps to make sure you have the necessary training and support to meet the requirements of the role.

28. 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.

[7] The Health Research Authority provides information and resources about the elements that should form part of early planning for research.

[8] Approval bodies include the Health Research Authority, the Administration of Radioactive Substances Advisory Committee (ARSAC), the Human Fertilisation and Embryology Authority (HFEA), or the Medicines and Healthcare products Regulatory Agency (MHRA).

29. Whatever your role, you should be satisfied that appropriate monitoring systems are in place to make sure research is being carried out in line with the law, the UK Policy Framework, and clinical practice.

Managing conflicts of interest

30. You must be open and honest in any financial and commercial dealings relating to your research and its funding. You must declare any commercial and non-commercial interests that you have in the project, in accordance with local and national governance arrangements.

31. You must not allow your judgement about the research to be adversely affected by conflicts of interest. You must:

    a. take care to identify actual or potential conflicts of interest, including between your responsibilities to participants and the wider public and:
        i. your own interests in the research project
        ii. your interests in any of the organisations involved in funding or supporting the project
    b. comply with your employing or contracting organisation's policies, and any external requirements (such as those of research funding or approval bodies, and research ethics committees), for identifying, declaring, and addressing conflicts of interest
    c. declare conflicts of interest as soon as possible
    d. if you're unsure whether a particular matter would be seen as a conflict of interest, act as though it is and seek advice from the relevant person or organisation on making a declaration.

32. You should also take into account any national guidance on the steps that researchers can take to avoid and manage conflicts of interest (see Annex B for examples).

33. You should act to make sure that commercial and other interests held by members of the research team, or the organisation funding or supporting the research, do not adversely affect the conduct of the research or its completion. If you're concerned about the effect of interests held by others, you should follow the approach in our guidance on *Raising and acting on concerns about patient safety*.

Recruiting participants

34. If you approach a patient to discuss the possibility of participating in a research project, you must share with them (or those representing the patient if they are not able to make the decision themselves), the information they need to understand the nature of the research and the benefits and risks of taking part. To do this effectively, you should have sufficient knowledge of the proposed research and its associated benefits and risks.

35. If you're responsible for obtaining consent, you must get this from potential research participants who have capacity to decide whether to take part. You must have other valid legal authority before you can involve an adult, or a child or young person, who does not have capacity to give consent to participating.[9]

36. In discussing potential participation, you must follow the guidance in *Decision making and consent* which promotes a person-centred, proportionate approach to providing information. The guidance makes clear that you must answer questions honestly and accurately, being clear about the limits of your knowledge. You must explain any uncertainties that a patient may want to consider in making their decision. Where relevant, you should also consider paragraphs 36–40 of *0–18 years: guidance for all doctors*, which deal with involving children or young people in research.

37. Where an approved research project involves an intervention that's different from the standard treatment or care that a patient might otherwise receive, you should provide potential participants with information explaining this aspect of the research design – so they can make a considered choice about whether to take part.

38. You must make sure that people are informed of their right to decline to take part in research, and their right to withdraw from a research project at any time. They must be advised that making these decisions will not affect their relationship with their usual doctor and healthcare team.

39. To support the overall safety and continuity of care for research participants, you should seek their consent to inform their general practitioner (or other clinician responsible for their care) about their involvement in the research project.

40. You should discuss with participants, or those representing them, who else you should consult if it becomes necessary to reconsider their participation in the project (also see paragraphs 44–45).

41. You must respect participants' rights to confidentiality. You must make sure that the collection, storage, and use of research participant information meets the requirements of data protection and privacy laws, and our guidance on *Confidentiality*.

Preventing harm

42. All members of a research team have individual and shared responsibilities for monitoring and reporting on participants' safety and well-being and any adverse events. This is in line

[9] The Health Research Authority and Medical Research Council provide joint guidance on consent and the preparation of information for research participants.

with guidance from the HRA, the MHRA or other relevant bodies. The sponsor of the research project and the employer of the members of a research team have responsibilities to make sure that safety and other reporting systems are in place – and to make sure appropriate action is taken in response to adverse events.

43. You should be clear about your role and the extent of your responsibilities for protecting research participants from harm. You should encourage open and honest incident reporting, so that issues can be acted on quickly, lessons learned, and improvements made; to increase the safety and quality of research, and maintain public confidence.

44. While there are both potential benefits and risks to research, it's possible that a research participant may experience unexpected, unwelcome side effects from a research intervention. Or the balance of risks and benefits of taking part in the research may change during the course of the project. If you become aware of this, whatever role you play in the project, you should make sure the participant has an early opportunity to discuss whether to continue with the research intervention, switch to another treatment, or withdraw from the project. You should also consult any persons it's been agreed you may communicate with (see paragraph 40). The participant's wishes or decisions must be respected.

45. You must keep under review the situation of research participants who may not be able to clearly communicate about unwelcome side effects, or other developments that may make it appropriate to consider whether to continue with a research intervention. You should discuss their experiences and options with any relevant persons it's been agreed you may consult, for instance, their carer or other representative (see paragraph 40).

46. Where it's within your power, you must stop research where the results (whether final or not) show that participants are at risk of significant harm or that no patient benefit can be expected from the intervention under investigation. Where stopping research is not within your power, you must promptly inform a relevant person[10] or authority that can act. You should also consider policies or rules for stopping research earlier than planned, which may apply. The safety of individuals must take priority over the interests of the research.

Honesty and transparency

47. You must conduct research honestly and with integrity. If you're concerned about the quality or integrity of a research project, including allegations of fraud or misconduct, you must follow our guidance on *Raising concerns*. You must report evidence of financial or scientific fraud, or other failures to follow the requirements of the UK Policy Framework, to an

[10] This will usually be the Chief Investigator or sponsor for the research.

appropriate person in your employing or contracting organisation and relevant regulatory bodies.

48. You must be open and honest with research participants and members of the research team, answering any questions accurately and as fully as possible.

49. 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 an appropriate period, to allow adequate time for review, further research, and audit, and to help resolve any concerns about the data or the research project. You should take account of any guidance on retention of research data that may apply to your research.[11]

50. You must report research results accurately, objectively, and in a way that can be clearly understood. You must make sure that research reports are properly attributed and do not contain false or misleading information.

51. You must report the outcome(s) of your research project to the register that holds the record of your approved proposal or protocol. You should seek to publish research results, including adverse findings, through peer-reviewed journals.

52. You must declare conflicts of interest when reporting research findings in publications.

53. You should make the findings of a research project publicly available, whatever the results. You should do this in a timely manner after the research has completed, taking account of participants' consent and privacy rights. You should make information about the findings available in a format that is accessible and easy to understand for any interested groups or communities, and the public.

54. If you're planning to communicate study findings directly to participants, you should respect any choices they've made about whether and how to receive this information.[12]

[11] For instance, the Medical Research Council provides guidance (see section 2B) on retaining data, which has been generated in the course of research it has funded. This includes retention periods.

[12] The Health Research Authority provides guidance on communicating study findings (results) to participants.

Annex A - Extracts from *Good medical practice*

Domain 1: Knowledge, skills and development

Introduction

Medical practice is a lifelong journey. Keeping pace with rapidly changing social, legal and technological developments means learning new skills while maintaining others. Sharing knowledge – gained through research and innovation, as well as experience – is fundamental to being a medical professional.

Good medical professionals are competent, keep their knowledge and skills up to date and provide a good standard of practice and care. They strive to develop and improve their professional performance. They reflect regularly on their standards of practice and use feedback and evidence to develop personal and professional insight.

Being competent

1. You must be competent in all aspects of your work including, where applicable, formal leadership or management roles, research and teaching.

Considering research opportunities

10. Research is vital in improving our understanding of health conditions, and increasing the availability of options for effective prevention, treatment, and care. You should consider opportunities to conduct or participate in research that may benefit current and/or future patients, and help to improve the health of the population. You should tell patients if you're aware of opportunities for them to participate in appropriate research.

Domain 2: Patients, partnership and communication

Supporting patients to make decisions about treatment and care

25. You must be satisfied that you have consent or other valid authority before examining or treating patients, or involving patients or volunteers in teaching or research. More detail about this is given in our guidance on *Decision making and consent* which you must follow. If relevant to your practice, you must also follow our guidance on *Making and using visual and audio recordings of patients*.

Sharing information with patients

35. If patients are asked to agree to be involved in teaching or research, you must share any information they'll need to make a decision and you must follow the guidance in paragraph 85 and our more detailed guidance on *Good practice in research*.

Domain 4: Trust and professionalism

Acting with honesty and integrity in research

85. When designing, organising or carrying out research, you must put the interests of participants first. You must act with honesty and integrity, and follow national research governance guidelines and our more detailed guidance on *Good practice in research*.

Annex B – Further resources

Patient and public involvement in research

The National Institute for Health and Care Research (NIHR) website describes different ways in which patients, carers and the public can get involved in research. It also contains a resource that can help people find out about health and social care research studies taking place across the UK.

Based on research by the University of Oxford, Healthtalk.org features videos where people talk about their experience of taking part in research as a patient or member of the public. They cover topics such as:

- what patient and public involvement (PPI) in research is, and why it matters
- different ways in which people can get involved in health research
- difficulties and barriers to involvement
- suggestions for professional health researchers.

Learning and training resources for people involved in research

The Health Research Authority's website signposts to several learning resources for the research community. This includes learning events and eLearning modules.

The NIHR provides various resources to help people develop their research knowledge and skills. This includes, for instance, training for people who are new to health and care research. There are also training courses on Good Clinical Practice (GCP) for people supporting clinical research delivery at the NHS, UK universities and other publicly funded organisations in England.

National guidance on addressing conflicts of interest in research

The following is a non-exhaustive list of guidance published by national bodies about addressing conflicts of interest in research:

- UK Research Integrity Office (UKRIO): Code of Practice for Research: Promoting good practice and preventing misconduct. UKRIO, 2023. Accessed May 2024. In particular, see Sections 3.5 (regarding competing interests), 3.13.5 (regarding peer review), and 3.14.10 (regarding dissemination of research outputs).
- UK Research Integrity Office (UKRIO): Recommended Checklist for Researchers. UKRIO, 2023. Accessed May 2024.
- British Medical Association: Transparency and doctors with competing interests – guidance from the BMA. BMA, 2024. Accessed May 2024.
- Medical Research Council: MRC ethics series. Good research practice: Principles and guidelines. MRC, 2014. Accessed May 2024. In particular, see section J (Conflicts of interest).
- Health Research Authority: Integrated Research Application System (IRAS): Collated Question-specific guidance for IRAS Form. Accessed May 2024. In particular, see Question A47 – Payment to researchers, and Question A48 - Conflicts of interest.
- National Research Ethics Advisors' Panel: Conflict of Interests/Competing Interests. Health Research Authority, 2012. Accessed May 2024. According to the guidance, it 'sets out a number of principles and possible solutions that might be applied by RECs [Research Ethics Committees] when considering how conflicts of interests/competing interests should be managed.'

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You are welcome to contact us in Welsh. We will respond in Welsh, without this causing additional delay.

Mae croeso i chi gysylltu â ni yn Gymraeg. Byddwn yn ymateb yn Gymraeg, heb i hyn achosi oedi ychwanegol.

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