

*Research Governance
Framework
for
Health and Social Care*

Second edition, 2005

Foreword

The Research Governance Framework outlines principles of good governance that apply to all research within the remit of the Secretary of State for Health. Research governance is one of the core standards for health care organisations.

This second edition takes account of several developments. Much published guidance refers to health research, and particularly clinical trials. Regulations on clinical trials involving medicines took effect in 2004. The change in the law stimulated wide debate on good practice and risk-based regulatory process. We have drawn lessons throughout this edition.

The Research Governance Framework remains grounded on principles that apply generally to research in health and social care. It applies to the full range of research types, contexts and methods. While research across health and social care should meet the same general standards of governance, there are also important differences. The mechanisms by which we achieve the standards depend on the context. I am delighted an implementation plan for research governance in social care has been published.

There has been new legislation on human tissue and on mental capacity, with provisions to protect those who participate in research. Whatever the context, the interests of research participants come first. Those responsible must be satisfied they have taken all reasonable steps to protect the dignity, rights, safety and well-being of participants. We have to be frank about risks, and businesslike about managing them.

John Reid, the Secretary of State for Health, said in the House of Commons on 22 March 2004, “investment in research saves lives, and that is why the Government wishes to make Britain the best place for R&D and innovation”. Public confidence in research, built on internationally recognised standards of good practice, is vital if we are to achieve that ambition.

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RESEARCH GOVERNANCE:

- Sets out principles, requirements and standards
- Defines mechanisms to deliver them
- Describes monitoring and assessment arrangements
- Improves research and safeguards the public by:
 - enhancing ethical awareness and scientific quality
 - promoting good practice
 - reducing adverse incidents and ensuring lessons are learned
 - forestalling poor performance and misconduct
- Is for all those who:
 - design research studies
 - participate in research
 - host research in their organisation
 - fund research proposals or infrastructure
 - manage research
 - undertake research
- Is for managers and staff, in all professional groups, no matter how senior or junior
- Is for those working in all health and social care research environments, including:
 - primary care
 - secondary care
 - tertiary care
 - social care
 - public health.

1 PURPOSE AND SCOPE

- 1.1 The Government is committed to enhancing the contribution of research to health and social care. Research is essential to the successful promotion and protection of health and well-being, and also to modern, effective health and social care services. At the same time, research can involve an element of risk, both in terms of return on investment and sometimes for the safety and well-being of the research participants. Proper governance of research is essential to ensure that the public can have confidence in, and benefit from, quality research in health and social care. The public has a right to expect high scientific, ethical and financial standards, transparent decision-making processes, clear allocation of responsibilities and robust monitoring arrangements.
- 1.2 This document sets out a framework for the governance of research in health and social care. The framework applies to all research that relates to the responsibilities of the Secretary of State for Health. That is, research concerned with the protection and promotion of public health, research undertaken in or by the Department of Health, its non-Departmental Public Bodies and the NHS, and research undertaken by or within social care agencies. It includes clinical and non-clinical research; research undertaken by NHS or social care staff using the resources of health and social care organisations; and any research undertaken by industry, charities, research councils and universities within the health and social care systems that might have an impact on the quality of those services.
- 1.3 A core standard for health care organisations is that they have systems to ensure the principles and requirements of this research governance framework are consistently applied. Health care organisations have to take this standard into account in discharging their duty of quality under Section 45 of the Health and Social Care (Community Health and Standards) Act 2003.
- 1.4 The same principles apply across health and social care research, but the way in which the relevant standards are achieved will differ according to the research type, context and method. For example, compared with much research in the NHS, research in social care differs in scale, volume and funding, as well as in the mix of stakeholders, the organisational context and the range of academic disciplines. The arrangements and mechanisms for implementing research governance in social care research are likely to have features that are particular to social care.

- 1.5** The aim of this framework is to bring together general principles of good practice. It refers to the law on clinical trials involving medicines. That does not mean it imposes the same procedures on other research when the interests of participants and the research methods do not call for them. The checklists of responsibilities in section 3 are there to help everyone reach agreement on arrangements that are proportionate to risk, and in line with good clinical practice. Therefore, the framework is offered also as a model for the governance of research in areas outside the direct responsibility of the Secretary of State for Health where poor practice could have a direct impact on the health or well-being of the public.
- 1.6** The framework is of direct relevance to all those who host, conduct, participate in, fund and manage health and social care research. It is not just for investigators, managers or any one professional group. All service and academic staff, no matter how senior or junior, have a role to play in the conduct of research. Participants in research and the public in general can also help to ensure that standards are understood and met.
- 1.7** This framework seeks to promote improvements in research quality across the board. As with clinical governance and best value in social care, research governance involves bringing general performance up to that of those at the leading edge. The framework provides a context for the encouragement of creative and innovative research and for the effective transfer of learning, technology and best practice to improve care.
- 1.8** The framework aims to forestall poor performance, adverse incidents, research misconduct and fraud, and to ensure that lessons are learned and shared when poor practice is identified. Learning from adverse events will promote good practice, enhance the ethical and scientific quality of research, and safeguard the public.
- 1.9** Health and social care generate and draw on a wide range of innovative work and ideas from professionals, organisations and the public. Services must promote innovation while protecting participants from risk and waste. Innovation embraces a much wider range of activities than those managed formally as research.
- 1.10** Research can be defined as the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods¹. This document sets out the responsibilities and standards that apply to work managed within the formal research context. Other documents on quality and governance in the NHS and social care set out standards and systems for assuring the quality of innovative work in non-research contexts.

¹ This definition includes studies that aim to generate hypotheses as well as studies that aim to test them.

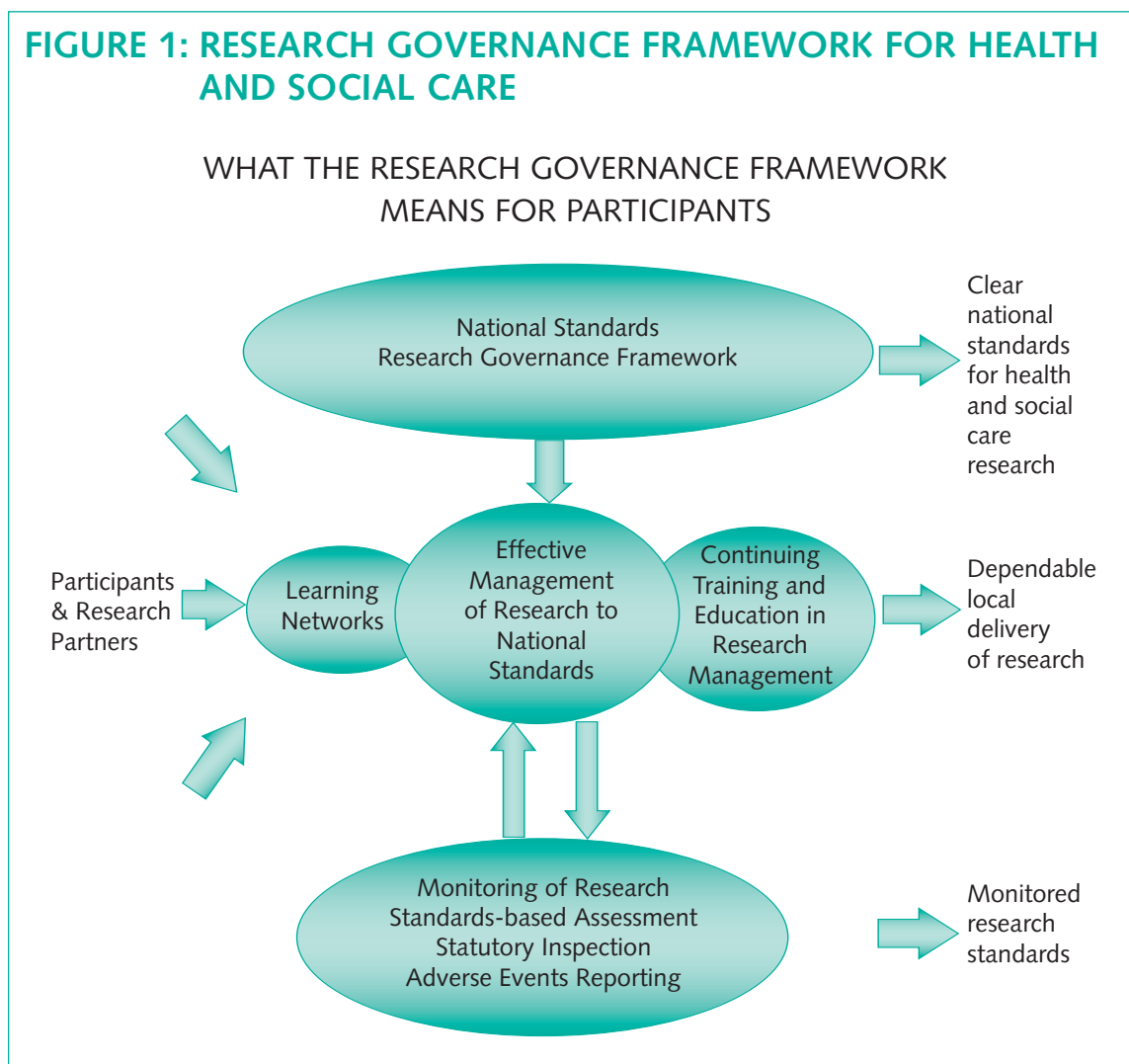
- 1.11** In common with other quality assurance and governance systems, this research governance framework describes:
- arrangements to define and communicate principles, requirements and standards;
 - delivery mechanisms to ensure that these are met², and
 - arrangements to monitor quality and assess adherence to standards nationally.
- 1.12** Enquiries into adverse incidents relating to research have criticised a lack of clarity about responsibility and accountability for research in health and social care. This is important, given the very wide range of individuals and organisations that can be involved. The framework pays particular attention to clarifying responsibilities and accountabilities.
- 1.13** Listed are some of the individuals and organisations involved in health and social care research:
- patients/users, their relatives, carers and organisations representing them;
 - the public;
 - research workers;
 - universities;
 - students and their supervisors;
 - research ethics committees;
 - research charities;
 - research councils;
 - health and social care professionals and professional organisations;
 - health and social care organisations;
 - local authorities;
 - the pharmaceutical and other industries;
 - the Department of Health.

² There are different delivery mechanisms for different aspects of research in health care, and for research in social care.

1.14 Achieving high quality in research depends on co-operation between all those involved. Figure 1 illustrates how the Department of Health will continue to work with patients, service users, carers and care professionals, the public and its research partners to develop and implement this research governance framework to assure quality in health and social care research.

1.15 Following the model in Figure 1, the rest of this document is structured as follows.

- Section 2 (with the Annex) sets out standards.
- Section 3 details responsibilities and accountability.
- Section 4 outlines delivery systems.
- Section 5 describes local and national monitoring systems.



2 STANDARDS

2.1 INTRODUCTION

2.1.1 *National Standards, Local Action* (DH, 2004) announced a new performance framework for the NHS and social care, driven by the core standards and developmental standards set out in *Standards for Better Health*. Research governance is one of the core standards for health care.

2.1.2 The Annex lists detailed principles and requirements for different aspects of research governance. It includes legislative requirements, Department of Health requirements, and statements of recognised good practice from a variety of established sources. Professional judgement is involved in the interpretation of this guidance. Quality in research depends on those responsible being appropriately qualified, with the skills and experience to use their professional judgement effectively in the delivery of dependable research.

2.1.3 Health and social care research is not the province of a single discipline, profession or organisation and no single document adequately captures the full range of legislation, standards and good practice guidelines that apply to this wide-ranging body of work. They are presented here in five domains:

- ethics;
- science;
- information;
- health, safety and employment;
- finance and intellectual property.

Where available, the Annex includes web-site addresses for the current standards, legislation and guidance listed in the domains. Where these relate to more than one domain they have been cross-referenced.

2.1.4 Each domain has been grouped as follows:

- requirements in legislation and regulations;

- standards required by the Department of Health;
- other established principles of good practice from recognised international and national authorities and professional organisations.

2.1.5 The Annex will be updated regularly. The following sections set out principles in each domain.

2.2 ETHICS

2.2.1 The dignity, rights, safety and well-being of participants must be the primary consideration in any research study. Box A (see page 10) describes a scenario to illustrate good practice in protecting research participants' rights within a study.

2.2.2 The Department of Health requires that research involving patients, service users, care professionals or volunteers, or their organs, tissue or data, is reviewed independently to ensure it meets ethical standards.³

2.2.3 Informed consent is at the heart of ethical research. Most studies involving individuals must have appropriate arrangements for obtaining consent, and the ethics review process pays particular attention to those arrangements.⁴ The law gives special protection to people who are unable to give consent on their own behalf. The Mental Capacity Act 2005 is to come into force in 2007. It will provide safeguards for a person who lacks capacity to consent to research.⁵ Researchers will have to respect the person's previous wishes, and will have to consult someone, such as a carer, who is able to take an independent view of the incapacitated person's interests, wishes and feelings.⁶ Care is needed when seeking consent from children and from vulnerable adults, such as those with mental health problems or learning difficulties. Arrangements must be made to ensure that relevant information is provided in appropriate written or pictorial form, and that the role and responsibilities of parents, carers or supporters are clearly explained and understood.

³ Under the Medicines for Human Use (Clinical Trials) Regulations 2004, it is against the law to start or conduct a clinical trial or to recruit participants to a clinical trial involving a medicine until there is a favourable opinion from an ethics committee and authorisation from the licensing authority.

⁴ Regulations under Section 60 of the Health and Social Care Act 2001 specify the very limited circumstances when identifiable patient information may be used for research without consent. The Patient Information Advisory Group considers such cases.

⁵ Also, under the Medicines for Human Use (Clinical Trials) Regulations 2004, specific conditions and principles apply to informed consent, and to the recruitment of minors and incapacitated adults.

⁶ There will be a legal requirement for review by an appropriate body – normally a research ethics committee – and for researchers to follow a statutory Code of Practice. The Code will specify research that can continue after loss of capacity.

- 2.2.4** Care is also needed when research involves tissue or organs. The Human Tissue Act 2004 is to come into effect in 2006. Current good practice should ensure that research complies with the Act before it takes effect. For the use of tissue from patients, the consent of the patient is required except in the circumstances specified in the Act, such as when a research ethics committee has agreed to the study and the samples are anonymised. For the use of tissue taken post mortem, the consent of the person concerned before they died, or of the relatives of the deceased, must always be obtained. Agreeing to such research involves relatives in difficult choices. Arrangements must be described for the respectful disposal of material once the research is completed, and for the reporting of the findings of the research to relatives, if they wish it. The new Human Tissue Authority is responsible for regulating and giving guidance on the storage and use of human tissue and organs.
- 2.2.5** The appropriate use and protection of patient data is also paramount. All those involved in research must be aware of their legal and ethical duties. Particular attention must be given to systems for ensuring confidentiality of personal information and to the security of those systems.
- 2.2.6** Relevant service users and carers or their representative groups should be involved wherever possible in the design, conduct, analysis and reporting of research. Social care research has a long tradition of involving them. INVOLVE, formerly Consumers in NHS Research, has established the principle that major advisory bodies in NHS R&D programmes should normally have at least two consumer representatives.
- 2.2.7** Research, and those pursuing it, should respect the diversity of human society and conditions and the multi-cultural nature of society. Whenever relevant, it should take account of age, disability, gender, sexual orientation, race, culture and religion in its design, undertaking, and reporting. The body of research evidence available to policy makers should reflect the diversity of the population.
- 2.2.8** Some research may involve an element of risk to those participating in it. If there are any risks to participants, the risks must be in proportion to the potential benefit.⁷ Risks, pain or discomfort must always be kept to a minimum, and explained clearly both to the relevant research ethics committee⁸ and to participants. It must always be explained whether there are arrangements for compensation in the unlikely event of non-negligent harm.

⁷ Unless the risk to them is negligible, it is unethical to involve adults without capacity to consent, or minors, in research that could have no therapeutic benefit for the group involved.

⁸ Or other ethics reviewer, when an NHS Research Ethics Committee opinion is not required.

2.2.9 Some essential research into important illnesses and treatments can be conducted only with animals. When undertaking research which could involve the use of animals, three principles should be followed:

- replacement of animals by non-animal methods wherever possible;
- reduction of numbers to the minimum necessary to obtain valid results where replacement is not possible; and
- refinement of all procedures to minimise adverse effects.

Wherever possible, alternatives such as cells, tissues, computers, bacteria and plants must be used instead. When animal use is unavoidable, there are strict controls enforced by the Home Office. Before a researcher can use animals, a series of special licences must be obtained. Primates are only to be used if less advanced animals could not provide the information. Researchers must have the necessary skills, training and experience, and the research laboratory must have the facilities to care for the animals properly. The highest standards of animal husbandry and welfare under veterinary supervision must be maintained and an ethical review process must operate in accordance with the Home Office requirements in the Annex.

BOX A: PROTECTING RESEARCH PARTICIPANTS' RIGHTS

What does it really feel like to be asked to participate?

Scenario *The Department of Health funded a social work professor to study social care services for parents of children with disabilities. The research team wished to interview parents, and children aged between 8 and 14 years.*

The research team obtained approval for the study from the Association of Directors of Social Services (ADSS) multi-site research committee. The team then contacted a sample of local councils, who agreed to send information about the proposed study to all parents of disabled children receiving social care services. The information covered the aims of the project, interview arrangements/topics, and issues of consent and confidentiality. Those interested in taking part were invited to reply directly to the researcher, indicating if they wished him/her to phone them to discuss the research further.

The researcher then sent additional information to those parents who agreed to take part, including an information pack for the child. The pack provided explanations about the research in different age-related formats.

Parent: I've read the information, I think I understand it, but there are a few points I'm not sure about. I think my child may be keen to take part, but I'm worried she might find it upsetting.

Researcher: I can't really say there's no possibility of something coming up that she may find upsetting. But if your daughter finds a question upsetting she won't have to answer it and she can stop the interview at any time. At the start of the interview we'll help her to rehearse telling us that she doesn't want to answer particular questions or that she doesn't want to go on. In the information sheet we noted down some of the topics we want to cover. Is there anything about your daughter's experience that might be particularly helpful for the interviewer to be aware of?

Cont.

BOX A: PROTECTING RESEARCH PARTICIPANTS' RIGHTS (cont.)

Parent: No, I can't think of anything ..., but will you tell me what she says?

Researcher: No, we'll reassure her that whatever she says won't be repeated to you, a social worker, or anyone else she knows. We'll tell her we have a duty to report some things under the Children Act. We'll also let her know that *she* can tell other people about the interview if she wants to. If she talks about any problems which it seems you or other people aren't aware of, we'll explore whether she wants to talk about them with anybody else and, if appropriate, we'll gently encourage her to do so. In our other research with children we've found that once they've talked about a problem during an interview they're usually quite keen to talk about it with someone else.

Parent: How do I know it'll be worthwhile?

Researcher: At present, we know very little about children's views of social care services for parents of children with disabilities. We particularly need to know if support services need to be improved for parents of children with disabilities and their families. The study's been commissioned by the Department of Health and the findings will be fed directly into the Government's review of social care services for parents of children with disabilities. A panel of experts checked the scientific design, and it has undergone ethics review.

Parent: If she says 'yes', can she pull out later?

Researcher: Yes. She can change her mind whenever she wants. We put that in writing for you and your daughter.

Parent: When the study's finished, will you tell us what you've found out?

Researcher: Yes, there'll be a summary of our findings written for the families who've taken part.

Parent: Do I have to make my mind up now?

Researcher: No, we don't need to know today, but it would be helpful if we knew by the 20th of next month – that's about four weeks away. Think about it for a while and call me again if you have any more questions. *Cont.*

BOX A: PROTECTING RESEARCH PARTICIPANTS' RIGHTS (cont.)

Scenario *A week or so later the parent decided to pass on the information pack about the study to her eight-year-old daughter. This introduced the research team and explained that they were writing a book about social care services for parents of children with disabilities. It also explained the purpose and scope of the interview, and arrangements for gaining their consent and protecting their confidentiality. A few days later the child rang with her own questions:*

Child: How long do you want to talk to me?

Researcher: For about an hour, but if you've only a few things to say it could be less than an hour. If you have a lot to say it could take longer.

Child: Will you tell anyone what I say?

Researcher: No one outside the research team will know your name. People will read about the things you say to us, but they will not know who said those things. You can choose whether *you* tell anyone else. The only thing is, we do have to report it if you say someone has broken the law.

Child: Will you write down what I say?

Researcher: Maybe, but we'd really like to tape what you say if that's OK with you.

Child: Will anybody reading the book know me?

Researcher: No one will know your name except us.

Child: Will you all come to speak to me?

Researcher: No, just one of us.

Child: What if I'm not sure? Can I change my mind?

Researcher: Yes, of course. Take your time if you are not sure. We don't need to know straight away. Talk to someone else about it if that helps. It would be helpful if you could let me know in about three weeks' time. If I have not heard from you by the 20th, I will take it that you've decided that you don't want to take part. If you do decide to take part, you can change your mind at any time.

2.3 SCIENCE

- 2.3.1** All existing sources of evidence, especially systematic reviews, must be considered carefully before undertaking research. Research which duplicates other work unnecessarily, or which is not of sufficient quality to contribute something useful to existing knowledge, is unethical.
- 2.3.2** Every proposal for health and social care research must be subjected to review by experts in the relevant fields able to offer independent advice on its quality. Arrangements for peer review should be in proportion to the scale of the research and the risks involved. For example, in some circumstances, an external panel of independent experts may be invited to review a programme or a controversial or costly proposal. In others, many organisations allow established research teams to determine details of the elements of an overall programme of research which has been reviewed externally. For student research projects, the university supervisor is normally able to provide adequate review.
- 2.3.3** The Medicines for Human Use (Clinical Trials) Regulations 2004⁹ regulate trials of medicines on people. Authorisation by the Medicines and Healthcare products Regulatory Agency is required. The Agency offers advice and undertakes inspections for such trials – and the manufacture and assembly of products used in them – against international standards. The same Agency regulates research involving new medical devices. The principles of Good Clinical Practice apply to all research involving patients, not just clinical trials.¹⁰
- 2.3.4** Special regulations govern the use of human embryos, the release of genetically modified organisms and food or food processes. Further information is in the Annex.
- 2.3.5** Data collected in the course of research must be retained for an appropriate period, to allow further analysis by the original or other research teams subject to consent, and to support monitoring by regulatory and other authorities. Guidance on storage is in the Annex.

⁹ The Medicines for Human Use (Clinical Trials) Regulations 2004 transposed Directive 2001/20/EC into UK law.

¹⁰ The Medical Research Council issued guidelines in 1998 for Good Clinical Practice in clinical trials in the public and charity sectors. The MRC guidelines apply the principles of Good Clinical Practice in the 1996 statement of the International Conference on Harmonisation (ICH GCP).

2.4 INFORMATION

- 2.4.1** Health and social care research is conducted for the benefit of patients, users, care professionals, and the public in general. There should be free access to information both on research being conducted¹¹ and on the findings of the research – positive or negative – once these have been subjected to appropriate scientific review. This information should be presented in a format understandable to the public. Reports need to be comprehensible, and to take language and other needs into account.
- 2.4.2** Some advances in health and social care need to be developed commercially if they are to be made widely available. Medicines, medical devices and aids for disabled people are examples. Successful commercial development often depends upon the protection of intellectual property or commercial confidentiality at critical points in the innovation process. The timing of the publication of research findings needs to take account of this.
- 2.4.3** All those conducting health and social care research must open their work to critical review through the accepted scientific and professional channels. Once established, findings must be made accessible to those participating¹² and to all those who could benefit from them. This may be through publication and/or other means appropriate to the type of research. Data relevant to findings should also be accessible.

2.5 HEALTH AND SAFETY

- 2.5.1** Research may involve the use of potentially dangerous or harmful equipment, substances or organisms. The safety of participants and of research and other staff must be given priority at all times, and health and safety regulations must be strictly observed – including the provision of information, containment, shielding and monitoring as required.

2.6 FINANCE

- 2.6.1** Financial probity and compliance with the law and with the rules set out by HM Treasury for the use of public funds are as important in research as in any other area.

¹¹ There is an international consensus that, with certain exceptions, information identifying a clinical trial of a treatment should be available on a public register from the time the first participant is recruited.

¹² Including the relatives of deceased patients who have consented to the use of organs or tissue in the research.

2.6.2 Organisations employing researchers must be in a position to compensate anyone harmed by their negligence. If any organisation offers to compensate participants in the event of non-negligent harm, it must be in a position to do so.

2.6.3 Consideration must be given to the exploitation of intellectual property rights.¹³

2.7 QUALITY RESEARCH CULTURE

2.7.1 Some of the principles and requirements set out in the Annex are clear-cut. Many require judgement and interpretation. A quality research culture, where excellence is promoted and where there is visible and strong research leadership and expert management, is essential if researchers and managers are to understand and apply standards, principles and requirements correctly.

2.7.2 The key elements of a quality research culture are:

- respect for participants' dignity, rights, safety and well-being;
- valuing the diversity within society;
- personal and scientific integrity;
- leadership;
- honesty;
- accountability;
- openness;
- clear and supportive management.

Promotion of these principles and values is as important as the detailed standards in the Annex.

2.7.3 Box B illustrates how research is managed in a health or social care organisation with a quality research culture. A quality research culture is essential for proper governance of health and social care research.

¹³ Guidance to the NHS is set out in the document *The NHS as an Innovative Organisation: A Framework and Guidance on the Management of Intellectual Property in the NHS* (DH, 2002).

BOX B: FEATURES OF A QUALITY RESEARCH CULTURE IN THE NHS AND SOCIAL CARE

Quality Research Culture

- The organisation supports and promotes high quality research as part of a service culture receptive to the development and implementation of best practice in the delivery of care. There is strong leadership of research and a clear strategy linking research to national priorities and needs, the organisation's business, and to clinical governance (in NHS organisations) and delivery of best value (in social care).
- The organisation's research strategy values diversity in its patients or service users and its staff, and promotes their active participation in the development, undertaking and use of research.

Ethics

- All research involving patients, service users, carers or care professionals and other staff, or their organs, tissue or data, is referred for independent ethical review to safeguard their dignity, rights, safety and well-being.
- Consent is sought in the way agreed during ethical review.
- Research is pursued with the active involvement of service users and carers including, where appropriate, those from hard-to-reach groups such as homeless people.
- If organs or tissue are used following post-mortems, informed consent is obtained from relatives, and there is a commitment to respectful disposal of material.
- If using animals is unavoidable, the highest standards of animal husbandry are maintained under veterinary supervision.

Science

- There is commitment to the principle and practice of scientific review by independent experts, with scrutiny of the suitability of protocols or proposals and research teams for all work in the organisation.
- There is close collaboration with partner organisations in higher education and care to ensure quality and relevance of joint work and avoidance of unnecessary duplication of functions.

Cont.

BOX B: FEATURES OF A QUALITY RESEARCH CULTURE IN THE NHS AND SOCIAL CARE (cont.)

- The organisation's human resource strategy includes commitment to support research careers (full and part-time) by earmarking funds specifically for R&D training across the professions. The organisation plays its role in developing research capacity with appropriate training and updating. This includes taking action to ensure that the diversity of the workforce reflects society, and developing the capacity of consumers to participate.
- The organisation promotes a high standard of health and safety in laboratory work. It follows Good laboratory Practice, Good Manufacturing Practice in manufacturing products for clinical trials, and Good Clinical Practice in conducting clinical trials.
- Systems are in place to monitor compliance with standards and to investigate complaints and deal with irregular or inappropriate behaviour in the conduct of research.
- The organisation assesses its research outputs and their impact and value for money.

Information

- Information is available on all research being undertaken in the organisation. It is held on a database containing details of research providers, funding, intellectual property rights, recruitment, research outputs and impact.
- The organisation ensures patients, service users and carers, care professionals and other staff have easy access to information on research. Where necessary, special arrangements are made to ensure access to information for those who do not have English as a first language, cannot read, or may need information in different formats because of a disability eg Braille.
- An information service provides access from a single point to all up-to-date regulatory and advisory documentation pertaining to research governance, together with procedural guidance, for example, for applications for ethical approval.
- When established, findings (including negative findings) are published in ways that allow critical review and dissemination to those who could benefit from them. Other researchers have access to the data on which the findings are based.
- There is a strategy for making research findings accessible. It addresses different media and writing styles for different audiences. Unless the research ethics committee agrees otherwise, those consenting to be involved in a study (including the relatives of deceased patients who have consented to the use of organs or tissue in the research) have ready access to the findings at the end of the study.

Cont.

BOX B: FEATURES OF A QUALITY RESEARCH CULTURE IN THE NHS AND SOCIAL CARE (cont.)

Finance

- The organisation is aware of the activity involved in supporting research and of what it costs. Research expenditure is planned and accounted for.
- The organisation demonstrates financial probity and compliance with the law and rules set out by HM Treasury. It complies with all audit required by external funders or sponsors and has systems to deter, detect and deal with fraud.
- When research findings have commercial potential the organisation takes action to protect and exploit them, in collaboration with its research partners and – when appropriate – commercial organisations.

3 RESPONSIBILITIES AND ACCOUNTABILITY

3.1 GENERAL

- 3.1.1** Everyone involved in research with human participants, their organs, tissue or data is responsible for knowing and following the law and the principles of good practice relating to ethics, science, information, health and safety, and finance set out in this framework.
- 3.1.2** All those involved in research also have a duty to ensure that they and those they manage are appropriately qualified, both by education and experience, for the role they play in relation to any research. They must be aware of, and have ready access to, sources of information and support in undertaking that role.

3.2 AGREEMENTS

- 3.2.1** A complex array of organisations and individuals may be involved in a health or social care research study. It is essential that clear agreements describing allocation of responsibilities and rights are reached, documented and enacted.
- 3.2.2** Many agreements will relate to individual studies. Organisations that collaborate on a range of research work are encouraged to develop and document framework agreements that clear the way for specific studies. For example:
- NHS foundation trusts, NHS trusts, primary care trusts and practices, and strategic health authorities that work together regularly on research, whether or not in a formal network;
 - universities and NHS foundation trusts, NHS trusts, primary care trusts and practices, research networks and strategic health authorities that work together regularly on research;
 - local authorities and/or other social care providers, strategic health authorities and primary care trusts and practices, that work together regularly on research whether or not in a formal research network; and
 - universities, local authorities and other social care providers that work together regularly on research.

3.2.3 It is particularly important to reach clear, documented agreements for complex studies where there may be:

- work on more than one site; and/or
- researchers employed by more than one organisation; and/or
- patients, service users and carers, and care professionals from more than one care organisation; and/or
- more than one funder.

A recommended approach is for a scheme of organisation in the protocol to include a detailed allocation of responsibilities. Each site can then subscribe to its own responsibilities by an exchange of letters that refers to the protocol.

3.2.4 The NHS R&D Partnership with the Pharmaceutical Industry sets out principles for industry involvement in commercial contract research and in collaborative studies. For contract clinical trials in secondary care, clinical trial agreements will be between the commercial sponsor and each NHS body accountable for the care of NHS patients participating in the trial. In primary care, these contracts will normally be between the commercial sponsor and General Practitioners or Practices. For collaborative studies with a contribution from industry, the commercial partner's contract may be with a university or NHS body depending on the circumstances. See the Annex for details of the NHS R&D Partnership with the Pharmaceutical Industry.

3.3 SPECIFIC RESPONSIBILITIES

3.3.1 Box C describes the terms used in this research governance framework for the main people and organisations involved in a health or social care research study.

3.3.2 The key responsibilities of the people and organisations accountable for the proper conduct of a study are in Box D. The remainder of section 3 sets out their responsibilities in more detail. Box E illustrates the responsibilities with a scenario.

BOX C: A TO Z OF THE MAIN PEOPLE AND ORGANISATIONS INVOLVED IN A HEALTH OR SOCIAL CARE RESEARCH STUDY

Chief investigator

The person who takes overall responsibility for the design, conduct and reporting of a study if it is at one site; or if the study involves researchers at more than one site, the person who takes primary responsibility for the design, conduct and reporting of the study, whether or not that person is an investigator at any particular site.

Employing organisation

Organisation employing the chief investigator, investigators or other researchers. Employers remain liable for the work of their employees. The organisation employing the chief investigator normally holds the contract or grant agreement with the funder of the study. Organisations holding contracts with funders remain responsible for the management of the funds provided.

Funder

Organisation providing funding for a study (through contracts, grants or donations to an authorised member of the employing and/or care organisation). The main funder typically has a key role in scientific quality assurance. In any case, it remains responsible for securing value for money.

Investigator

Person responsible, individually or as leader of the researchers at a site, for the conduct of a study at that site. For clinical trials involving medicines, an investigator must be an authorised health professional.

Organisation providing care

Organisation responsible for providing health or social care to patients and/or service users and carers participating in a study. Health and social care organisations remain liable for the quality of care, and for their duty towards anyone who might be harmed by a study.

Cont.

BOX C: A TO Z OF THE MAIN PEOPLE AND ORGANISATIONS INVOLVED IN A HEALTH OR SOCIAL CARE RESEARCH STUDY (cont.)

Participant

Patient, service user, carer, relative of the deceased, professional carer, other employee, or member of the public, who consents to take part in a study. (In law, participants in clinical trials involving medicines are known as subjects.)

Principal investigator

The leader responsible for a team of individuals conducting a study at a site.

Researchers

Those conducting the study.

Research ethics committee

Committee established to provide participants, researchers, funders, sponsors, employers, care organisations and professionals with an independent opinion on the extent to which proposals for a study comply with recognised ethical standards. For clinical trials involving medicines, the ethics committee must be one recognised by the United Kingdom Ethics Committee Authority.

Responsible care professional

Doctor, nurse, social worker or other practitioner formally responsible for the care of participants while they are taking part in the study.

Sponsor

Individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a study. (A group of individuals and/or organisations may take on sponsorship responsibilities and distribute them by agreement among the members of the group, provided that, collectively, they make arrangements to allocate all the responsibilities in this research governance framework that are relevant to the study.)

BOX D: SUMMARY OF KEY RESPONSIBILITIES OF PEOPLE AND ORGANISATIONS ACCOUNTABLE FOR THE PROPER CONDUCT OF A STUDY

Chief investigator, investigators, other researchers (see sections 3.5, 3.6)	<ul style="list-style-type: none">• Developing proposals that are scientifically sound and ethical.• Submitting the design for independent expert review.• Submitting the study (or proposal) for independent ethical review.• Conducting a study to the agreed protocol (or proposal), in accordance with legal requirements, guidance and accepted standards of good practice.• Preparing and providing information for participants.• Ensuring participants' welfare while in the study.• Arranging to make findings and data accessible following expert review.• Feeding back results of research to participants.
Main funder (see section 3.7)	<ul style="list-style-type: none">• Assessing the scientific quality of the research as proposed.• Establishing the value for money of the research as proposed.• Considering the suitability of the research environment in which the research will be undertaken, particularly the experience and expertise of the chief investigator, principal investigator(s) and other key researchers involved.• Requiring that a sponsor takes on responsibility before the research begins.
Sponsor (see sections 3.8, 4.3)	<ul style="list-style-type: none">• Confirming that everything is ready for the research to begin:<ul style="list-style-type: none">– taking on responsibility for putting and keeping in place arrangements to initiate, manage and fund the study;– satisfying itself the research protocol, research team and research environment have passed appropriate scientific quality assurance;– satisfying itself the study has ethical approval before it begins;– for clinical trials involving medicines¹⁴, seeking a clinical trial authorisation and making arrangements for investigational medicinal products.• Satisfying itself that arrangements are kept in place for good practice in conducting the study, and for monitoring and reporting, including prompt reporting of suspected unexpected serious adverse events or reactions.

Cont.

¹⁴ The Medicines for Human Use (Clinical Trials) Regulations 2004 specify the responsibilities that have to be undertaken by or on behalf of sponsors of trials involving medicines.

BOX D: SUMMARY OF KEY RESPONSIBILITIES OF PEOPLE AND ORGANISATIONS ACCOUNTABLE FOR THE PROPER CONDUCT OF A STUDY (cont.)

Employing organisation (see section 3.9)

- Promoting a quality research culture.
- Ensuring researchers understand and discharge their responsibilities.
- Ensuring studies are properly designed and submitted for independent review.
- Ensuring studies are managed, monitored and reported as agreed, according to the protocol.
- Providing written procedures, training and supervision.
- Taking action if misconduct or fraud is suspected.

Organisation providing care/ Responsible care professional (see sections 3.10, 3.11, 4.4)

- Arranging for an appropriate person to give permission for research involving their patients, service users, carers or staff, before the research starts.
- Ensuring any such research is conducted to the standards set out in this research governance framework.
- Requiring evidence of ethical review before recruitment to any research that affects their duty of care.
- Before recruitment to trials with medicines, requiring evidence of a positive ethical opinion and a clinical trials authorisation.
- Retaining responsibility for the care of participants to whom they have a duty.

BOX E: SPECIFIC RESPONSIBILITIES OF KEY PEOPLE INVOLVED IN RESEARCH

WHO IS RESPONSIBLE FOR WHAT? SOME QUESTIONS AND ANSWERS

Scenario *The Medical Research Council (MRC) awards a university Senior Lecturer in General Practice a grant for a clinical trial of a medicine. The grant is paid to the university. The MRC was closely involved in developing the trial design, and the study conducted through a Primary Care Research Framework. The Medicines and Healthcare products Regulatory Agency (MHRA) has agreed that the university and the Framework form a group to take on the sponsor's responsibilities. The manufacturer of the drug has agreed to provide it free. The drug has a marketing authorisation covering the use of the product described in the research protocol. The research is taking place in general practices.*

PATIENT

Q: I did tell my GP I might be interested in joining the study. Does that commit me?

A: Your GP agreed to collaborate with the research team, and invite her patients to participate. Whether or not you agree is entirely up to you. Unless you consent, you won't be in the study.

Q: How can I know the study is worthwhile?

A: Through independent expert review ("peer review"), the MRC assessed the clinical importance of the questions addressed by the study. It also assessed the design and oversight arrangements. An ethics committee checked it is ethical. The MHRA authorised it.

Q: How can I find out more about it?

A: Please take away this patient information leaflet to study. You can ask your GP or anyone on the research team for further details.

Q: What if the drug involved does not agree with me?

A: Your GP is still responsible for your care. She knows how we plan to monitor people who are in the trial. We will tell her at once if we detect problems, and you can approach her at any time. It is important for you to say if you have a bad reaction to the drug.

Cont.

BOX E: SPECIFIC RESPONSIBILITIES OF KEY PEOPLE INVOLVED IN RESEARCH (cont.)

G.P.

Q: How do I know that this study is well designed?

A: The university and the Primary Care Research Framework are together sponsoring the study. The protocol names the sponsors' contact point. The scientific design went through the MRC's independent review system. It has ethical approval, and regulatory approval from the licensing authority. But you must decide whether you feel able to collaborate with it.

Q: Who is responsible for the care of my patients if they agree to take part?

A: You are. The protocol explains the procedures the research team will follow and the circumstances when they will alert you to anything they observe in your patients. You need to be satisfied with these arrangements. Discuss them with the Chief Investigator if you are not.

Q: I have agreed to join the study, but my patients are having trouble understanding what they are asked to take part in. It's taking up an enormous amount of time. What should I do?

A: You need to talk to the Chief Investigator. A better understanding of the consent process could resolve these issues. Perhaps communication with your patients could be improved, for example by revising the patient information leaflet. If the problem really can't be solved, you can withdraw.

Q: Who is responsible for ensuring the study follows the protocol, and data are monitored to detect any possible problems?

A: It is the Chief Investigator's job to make sure you and everyone involved in the study are well informed, and able to carry out their roles properly. This is a trial of a medicine, so there is a legal responsibility to follow the protocol. If you have any concerns about doing so, you should contact the Chief Investigator. If you are not satisfied, you should inform the sponsor's representative.

Cont.

BOX E: SPECIFIC RESPONSIBILITIES OF KEY PEOPLE INVOLVED IN RESEARCH (cont.)

G.P. (continued)

Q: Who is responsible for the quality of the drugs?

A: The pharmaceutical company supplying the drugs is responsible for their quality. Medicines have to be made in licensed facilities, and must be correctly labelled for trials.

Q: One of my patients seems much worse since I entered him into the trial. He is keen to continue, but I am concerned. What should I do?

A: Your primary responsibility is the patient's care. You have a duty to put his safety before anything required by the research. You should advise him to withdraw if you think that the trial drug caused his problems. Explain to him that you will talk to the research team on his behalf. It is very important you inform the chief investigator of any concerns about treatment under the trial. In trials of medicines, it is a legal requirement to report harmful reactions to the MHRA so that everyone can learn from them.

CHIEF INVESTIGATOR

Q: How do I know when the trial is authorised?

A: As it falls under the Medicines for Human Use (Clinical Trials) Regulations 2004, the trial has to be authorised by the MHRA. The MHRA notifies sponsors when trials are authorised. It is against the law for you to start recruiting until you know the MHRA has issued a Clinical Trial Authorisation. The sponsors' representative will tell you when the drugs can be released for use in the trial.

Q: What about ethical review?

A: You have submitted the study to an ethics committee, recognised for this kind of study, using the electronic form available on COREC's website. You need a positive ethics committee opinion as well as a Clinical Trial Authorisation before you can start the trial. (To come within NHS indemnity, you also need permission from each NHS site before you seek to recruit anyone covered by that organisation's duty of care.) *Cont.*

BOX E: SPECIFIC RESPONSIBILITIES OF KEY PEOPLE INVOLVED IN RESEARCH (cont.)

CHIEF INVESTIGATOR (continued)

Q: To whom must I report an adverse event?

A: For this trial, the sponsors have delegated to you the responsibility for recording and reporting adverse events. The MHRA will issue the Clinical Trial Authorisation on that basis, so you have to follow the agreed process for recording adverse events, assessing seriousness, relatedness and expectedness, and reporting. You must arrange to report any worrying reaction immediately to the patient's GP. Adverse drug reactions must also be reported to the Trial Steering Committee, the drug manufacturer, the MHRA, the ethics committee and the Data Monitoring Committee. Under the Clinical Trials Regulations, there is a legal obligation to report suspected unexpected serious adverse reactions (SUSARs) to the MHRA within a set period.

Q: I am concerned the staff in the university labs may not follow health and safety rules. What do I do?

A: You should raise this concern through the university's local health and safety systems.

Q: I am concerned not all the investigators will follow the protocol closely – what should I do?

A: Inform the sponsor's representative immediately and agree a course of action.

Q: If my team need training, to whom should I talk?

A: Their employer is normally responsible for their training.

Q: To whom do I talk if I suspect a university colleague is fabricating data?

A: Your university, as your colleague's employer, is responsible for investigating the suspected misconduct. Others such as the General Medical Council may also be responsible for looking into your suspicions if they appear to involve professional misconduct. If you suspect someone employed by another organisation, raise your concerns with your employer, who as sponsor will contact your colleague's employer. In any case, record the evidence carefully so that there can be a proper investigation.

Cont.

BOX E: SPECIFIC RESPONSIBILITIES OF KEY PEOPLE INVOLVED IN RESEARCH (cont.)

CHIEF INVESTIGATOR (continued)

Q: I have new information that makes me think we could improve the design of this study. What do I do?

A: Discuss it with the Trial Steering Committee. If they agree, you need to draw up a revised protocol, and submit it to the MRC. The sponsor's representative will then submit the amendment to the MHRA, and you need to go back to the relevant ethics committee. You must not implement substantial changes to the protocol without formal agreement from those who gave permission for the study (particularly the MHRA and the ethics committee). When an amendment is authorised you need to tell all investigators to follow the new protocol from a specified time.

Q: I may generate some important intellectual property (IP). What should I do?

A: Your employer is one of the sponsors and will have a policy on IP that complies with the terms of funding. You should refer to and comply with this policy, which is likely to be part of your conditions of employment. Your employer may have an IP unit that can help you follow the right procedures.

Q: What if the MHRA does a Good Clinical Practice inspection?

A: You must co-operate. The inspectors have legal powers to ask for documents and take enforcement action. Generally, they look for evidence of good systems that are proportionate to the risks involved. The MHRA will point out any improvements needed for trial sites to comply with the law. They seek a prosecution only if it would be in the public interest because of very serious or persistent failure.

3.4 RESPONSIBILITIES OF PARTICIPANTS

3.4.1 Effective and responsive services depend on good research. Through this framework and related provisions, the Government and its partners strive to ensure that research conducted in health and social care in England offers the likelihood of real benefits either to those who participate, or to those who use services subsequently, or both. Anyone using health and social care services should give serious consideration to becoming involved in developing or undertaking research studies.

3.4.2 Researchers are responsible for selecting means of communication that ensure potential participants are fully informed before deciding whether or not to join a study. In clinical trials involving medicines, there is a legal requirement to provide an interview with a member of the research team and a contact point offering further information about the trial. Potential participants should not hesitate to ask if they do not understand the information and explanations given. Guidance on research with children and others who may have difficulty understanding the information given is listed in the Annex.

3.5 RESPONSIBILITIES OF RESEARCHERS

3.5.1 Researchers bear the day-to-day responsibility for the conduct of research. They are responsible for:

- ensuring that any research they undertake follows the current version of the agreed protocol (or proposal);
- helping care professionals to ensure that participants receive appropriate care while involved in research;
- reporting any adverse drug reactions or other adverse events;
- protecting the integrity and confidentiality of clinical and other records and data generated by the research; and reporting any failures in these respects, or suspected misconduct, through the appropriate systems.

3.6 RESPONSIBILITIES OF INVESTIGATORS AND THE CHIEF INVESTIGATOR

3.6.1 A senior individual must be designated as the chief investigator for any research undertaken in or through the NHS or social services, which involves participants or their organs, tissue or data. This person normally takes responsibility for the conduct of the research at a site, and is accountable for it to their employer, and through them to the sponsor of the research. The chief investigator is also directly accountable to the care organisation(s) where the research takes place (or through which the research team has access to participants, their organs, tissue or data). If the research is at more than one site, the chief investigator takes on personal responsibility for the design, management and reporting of the study, co-ordinating the investigators who take the lead at each site.

3.6.2 Chief investigators must have suitable experience and expertise in the design and conduct of research¹⁵ so that they are able either to

- undertake the design, conduct, analyses and reporting of the study to the standards set out in this framework, or
- lead and manage others with delegated responsibility for some of these aspects.

3.6.3 For research in health or social care, the chief investigator is responsible for ensuring the following.

- The research team gives priority at all times to the dignity, rights, safety and well-being of participants.
- The study complies with all legal and ethical requirements.
- The research is carried out to the standards in this research governance framework.
- Each member of the research team, including those at collaborating sites, is qualified by education, training and experience to discharge his/her role in the study, and their qualifications are documented.
- Each investigator in a clinical trial involving medicines is aware of his/her legal duties.
- Students and new researchers have adequate supervision, support and training.
- The Chief Executive of the care organisation(s) involved and/or any other individual(s) with responsibilities within this framework are informed that the study is planned, and their permission is obtained before the research starts.
- When a study involves participants under the care of a doctor, nurse or social worker for the condition to which the study relates, those care professionals are informed that their patients or users are being invited to participate, and agree to retain overall responsibility for their care.
- When the research involves a service user or carer or a child, looked after or receiving services under the auspices of the local authority, the agency director or her deputy agrees to the person (and/or their carer) being invited to participate, and is fully aware of the arrangements for dealing with any disclosures or other relevant information.

¹⁵ For clinical trials involving medicines, the chief investigator and other investigators must be authorised health professionals as defined in the Medicines for Human Use (Clinical Trials) Regulations 2004.

- Potential participants and other service users and carers are involved in the design and management of the study whenever appropriate.
- The study is submitted for ethics review and it does not start without a favourable opinion, and the research team acts on any conditions attached to the ethics opinion.
- Unless participants or the ethics opinion says otherwise, participants' care professionals are given any information directly relevant to their care that arises in the research.
- Unless urgent safety measures are necessary¹⁶, the research follows the protocol or proposal agreed by the relevant research ethics committee and by the sponsor.¹⁷
- Substantive changes to the protocol or proposal are submitted for ethical review and for the sponsor's agreement. These amendments are implemented only when approved.¹⁸
- Controlled trials are registered, and for clinical trials involving medicines, the research follows any conditions imposed by the licensing authority.
- Procedures are kept in place to ensure collection of high quality, accurate data and the integrity and confidentiality of data during processing and storage.¹⁹
- Arrangements are kept in place for the management of financial and other resources provided for the study, including for the management of any intellectual property arising.
- Reports on the progress and outcomes of the work required by the sponsor, funders, or others with a legitimate interest are produced on time and to an acceptable standard.
- The findings from the work are opened to critical review through the accepted scientific and professional channels.
- The chief investigator accepts a key role in detecting and preventing scientific misconduct by adopting the role of guarantor on published outputs.

¹⁶ Investigators in clinical trials involving medicines have to report serious adverse events immediately.

¹⁷ For clinical trials involving medicines, it is a legal requirement to follow the protocol approved by the licensing authority (the Medicines and Healthcare products Regulatory Agency).

¹⁸ Also, for clinical trials involving medicines, to the licensing authority.

¹⁹ Also, for clinical trials involving medicines, procedures to comply with legal requirements concerning Good Clinical Practice during the trial, and Good Manufacturing Practice in manufacturing investigational medicinal products.

- Once established, findings from the work are disseminated promptly and fed back as appropriate to participants.
- There are appropriate arrangements to archive the data when the research has finished, and to make it accessible.
- All data and documentation associated with the study are available at the request of the inspection and auditing authorities.

3.7 RESPONSIBILITIES OF RESEARCH FUNDERS

3.7.1 Organisations that fund research have a responsibility to ensure that it is a proper use of the funds they control and provides value for money.

3.7.2 The main research funder plays a critical role in assuring the quality of a study. It will normally take the lead in establishing that the research proposal is worthwhile, of high scientific quality, and represents good value for money.²⁰

3.7.3 The main research funder is normally the organisation that makes arrangements for independent expert review to assess:

- the quality of the research as proposed;
- the experience and expertise of the Chief Investigator and other key researchers;
- whether there is appropriate research infrastructure for the study: for example, management and governance arrangements, access to potential participants (or their organs, tissue or data); specialised facilities such as equipment, materials or support staff; and
- for trials on medicines, expert clinical trial management and the capacity to comply with the principles of Good Clinical Practice.

If the main funder is unable to arrange for independent expert review, the sponsor is expected to arrange for it before taking on responsibility for the study, or to require another organisation to arrange for it. It is good practice for funders to make scientific judgements related to their responsibilities with expert advice independent of the investigators.

3.7.4 Funders are expected to provide assistance to any enquiry, audit or investigation related to the funded work.

²⁰ The value for money assessment compares the potential benefits with the resources that the study requires. These resources include any additional care or treatment costs, as well as the research costs that the funder is to meet.

3.7.5 Funders are expected to make their funding conditional on identifying a sponsor. Organisations wishing to fund research requiring the collaboration of the NHS or social care services in England will either take on sponsorship themselves, or collaborate with another organisation that is willing and able to do so. Potential collaborators may be other funders, or employers of researchers, including health or social care providers that have declared they are ready in principle to sponsor studies within programmes of research funded by the Department or the NHS.

3.8 RESPONSIBILITIES OF THE SPONSOR

3.8.1 The sponsor is the individual, or organisation (or group of individuals or organisations) that takes on responsibility for confirming there are proper arrangements to initiate, manage and monitor, and finance a study.²¹ For any research that takes place in the context of the NHS or social care services in England there must be a sponsor. Normally, the sponsor will be one of the organisations taking the lead for particular aspects of the arrangements for the study. It may be the Chief Investigator's employing organisation, or the lead organisation providing health or social care, or the main funder. If the sponsor is outside the United Kingdom, it must have a legal representative in the United Kingdom.²¹ For any research study covered by this research governance framework, it is for the sponsor to be satisfied that clear agreements are reached, documented and carried out, providing for proper initiation, management, monitoring and financing. Others will rely on reasonable assurances that the sponsor has taken steps to do this.

3.8.2 The sponsor is responsible for ensuring before a study begins that arrangements are in place:

- for the research team to access resources and support to deliver the research as proposed; and
- to allocate responsibilities for the management, monitoring and reporting of the research.

²¹ For clinical trials involving medicines, the sponsor is defined as the person (eg individual, institution, company or organisation) who takes responsibility for the initiation, management and financing (or arranging the financing) of that trial. Such sponsors have specific legal duties under the Medicines for Human Use (Clinical Trials) Regulations 2004. Regulation 3 defines options for sponsorship, including single sponsorship, joint sponsorship and allocation of sponsorship responsibilities within a group. The Regulations require a sponsor to be established, or have a legal representative, in the European Community. Neither of them need be established in the United Kingdom.

The sponsor also has to be satisfied there is agreement on appropriate arrangements to

- record, report and review significant developments as the research proceeds, particularly those which put the safety of individuals at risk; and to
- approve any modifications to the design, obtain any regulatory authority required, implement them, and make them known.

3.8.3 It is the sponsor's responsibility to be satisfied with the arrangements for management and monitoring. Normally, if the Chief Investigator's employer takes on the sponsor's responsibilities (alone or as a member of a group), it will assume responsibility for operating the management and monitoring systems in collaboration with the employers of other members of the research team. Exceptionally, it may be inappropriate for the Chief Investigator's employer to take responsibility for the management and monitoring of a study. In that case, the sponsor should make arrangements with one or more other organisations that will operate the management and monitoring systems.

3.8.4 Provided the sponsor keeps in place arrangements for performance management and audit, the responsibility for design and management may be delegated to the research team. The extent of delegation should be specified, even for a research team with proven expertise and track record. Commercial sponsors may arrange for their own audit processes.

3.8.5 When no external sponsor takes on responsibility for it, a study may proceed only if a health or social care organisation takes on sponsorship. For example, an NHS trust or a Council with Social Services Responsibilities (CSSR) may be willing and able to act as the sponsor for research that does not have an external sponsor (sometimes called "own account" research).

3.8.6 When research is for research training purposes, research supervisors normally carry out the sponsorship responsibilities on behalf of their employers. Exceptionally, a university may authorise a suitably experienced postgraduate student to carry out these responsibilities on its behalf.

3.8.7 It is the sponsor's responsibility to be satisfied that:

- The research proposal respects the dignity, rights, safety and well-being of participants and the relationship with care professionals.
- An appropriate process of independent expert review has demonstrated the research proposal to be worthwhile, of high scientific quality and good value for money.

- An appropriate research ethics committee or independent ethics reviewer²² has given a favourable opinion.
- In the case of a clinical trial involving a medicine, someone acting on behalf of the sponsor obtains a clinical trial authorisation, and the arrangements for the trial comply with the law.
- Appropriate arrangements are in place for the registration of a trial.
- The chief investigator, and other key researchers, including those at collaborating sites, have the necessary expertise and experience and have access to the resources needed to conduct the proposed research successfully.
- The arrangements and resources proposed will allow the collection of high quality, accurate data, and the systems and resources proposed are those required to allow appropriate data analysis and data protection.
- Arrangements proposed for the work are consistent with this research governance framework.
- Organisations and individuals involved in the research agree the division of responsibilities between them.
- There is written agreement about the arrangements for the management and monitoring of the study.
- Arrangements are in place for the sponsor and other stakeholder organisations to be alerted to significant developments²³ during the study, whether in relation to the safety of individuals or to scientific direction.²⁴
- Agreement has been reached about compensation in the event of harm to research participants²⁵; and if any organisation, or the sponsor itself, offers compensation without proof of negligence, it has made the necessary financial arrangements.

²² See section 3.12. The Department of Health is working with others to develop ethical review of social care research. If it is not possible to have a social care research proposal reviewed by an appropriate committee, it is the sponsor's responsibility to make other arrangements for independent ethical review.

²³ For clinical trials involving medicines, these include serious adverse events, serious adverse reactions, and suspected unexpected serious adverse reactions as defined in the Medicines for Human Use (Clinical Trials) Regulations 2004.

²⁴ For clinical trials involving medicines, the sponsor has a legal duty to record and report suspected unexpected serious adverse reactions as soon as possible. The sponsor also has to provide annually a list of all such reactions occurring in the past year, and a report on the safety of the participants in the trial.

²⁵ For clinical trials involving medicines it is a legal requirement that there should be insurance or indemnity to cover the liabilities of sponsors and investigators.

- There are arrangements for the conclusion of the study including appropriate plans for disseminating the findings.

Scientific judgements made by the sponsor in relation to these responsibilities should be based on independent and expert advice. The sponsor is expected to assist any enquiry, audit or investigation related to the funded work.

3.9 RESPONSIBILITIES OF UNIVERSITIES AND OTHERS EMPLOYING RESEARCHERS

3.9.1 Employers of staff undertaking health and social care research have responsibility for developing and promoting a high quality research culture in their organisation and for ensuring that their staff are supported in, and held to account for, the professional conduct of research. This involves careful attention to training, career planning and development, and the use of clear codes of practice and systems for monitoring compliance, dealing with non-compliance or misconduct, and learning from errors and complaints. These responsibilities apply to both private and public sector employers.

3.9.2 Organisations that employ chief investigators and other researchers have responsibility for ensuring that those researchers understand and discharge the responsibilities set out for them in this framework, and under the law. They may do this, for example, through terms of employment, staff handbooks, and training. They will normally take on some or all of the responsibility for ensuring that a study is properly managed and for monitoring its progress. When the employing organisation is not the sponsor, it should agree its responsibilities with the sponsor and the organisation(s) providing care. The sponsor has to be satisfied with the arrangements for the management of a study; and that there is agreement on appropriate arrangements for monitoring and reporting.²⁶

3.9.3 Employers should ensure there are agreements between them and their staff and between them and research funders and care organisations about ownership, exploitation and income from any intellectual property that may arise from research conducted by their employees. They have a responsibility for ensuring that employees identify and protect intellectual property.

²⁶ For clinical trials involving medicines, the sponsor has to put and keep in place arrangements for the purpose of ensuring that the conditions and principles of Good Clinical Practice are satisfied or adhered to.

3.9.4 Universities and other employers of staff engaged in research are responsible for:

- compliance with all current employment and health and safety legislation;
- demonstrating the existence of clear codes of practice in other areas for their staff, and mechanisms to monitor and assess compliance;
- ensuring that investigators and other research staff are aware of, understand and comply with this framework;
- discharging their agreed role in the management and monitoring of work undertaken by their organisation;
- demonstrating systems for continuous professional development of staff at all levels;
- having agreements and systems to identify, protect and exploit intellectual property;
- ensuring that they are able to compensate anyone harmed as a result of negligence on the part of staff, students and others for whom they have liability; and, if they have agreed to do so, to compensate participants for non-negligent harm arising from the research;
- Having systems to detect and address fraud, and other scientific or professional misconduct by their staff.
- Having systems to process, address and learn lessons from any errors or complaints brought against their employees.
- Permitting and assisting in any statutory inspection, audit, or investigation arising from errors or complaints associated with their employees.

3.10 RESPONSIBILITIES OF ORGANISATIONS PROVIDING CARE

3.10.1 It is the responsibility of organisations providing health or social care in England to be aware of all research undertaken in their organisation, or involving participants, organs, tissue or data obtained through the organisation. Primary Care Trusts are responsible for providing a safe system of care. Within it, care providers remain responsible for the quality of the care of their patients or service users and carers, whether or not individuals are involved in research and whoever conducts or funds that research. Health care organisations' duty of quality includes research

governance. They should ensure that their patients, service users and carers, and care professionals are provided with information about any research which may have a direct impact on their care, their experience of care, or their work in the organisation. They should ensure that activities are presented as research, only if they are managed as research within this framework.

3.10.2 Organisations providing care are responsible for satisfying themselves that they have adequate arrangements and resources for any research involving their patients, service users and carers, or staff to meet the standards set out in this framework. No health or social care research with human participants, their organs, tissue or data, may begin before

- an identified sponsor has taken on responsibility for that research,
- the study has received a positive ethical opinion, and
- the allocation of responsibilities is agreed and documented.

Accountability for this lies with the Chief Executive or Agency Director. He or she will normally delegate responsibility to a qualified and senior person.

3.10.3 A researcher not employed by any NHS organisation who interacts with individuals in a way that has direct bearing on the quality of their care should hold an NHS honorary contract.²⁷ When universities and health care organisations are both involved in employing clinical academic staff, they are expected to make joint arrangements for appointment, supervision and appraisal.²⁸

3.10.4 The responsibilities of organisations providing care are to:

- Retain responsibility for the quality of all aspects of participants' care whether or not some aspects of care are part of a research study.
- Maintain a record of all research undertaken through or within the organisation, including research that students undertake as part of their training.
- Ensure patients or users and carers have information on any research that may affect their care.

²⁷ If there is negligent harm during a study with NHS permission when the NHS body owes a duty of care to the person harmed, NHS Indemnity covers NHS staff, medical academic staff with honorary contracts, and those conducting the study.

²⁸ When universities and hospitals employ staff on joint or dual contracts, they are expected to make joint arrangements for accountability and management. See *A Review of Appraisal, Disciplinary and Reporting Arrangements for Senior NHS and University Staff with Academic and Clinical Duties*, a report to the Secretary of State for Education and Skills by Professor Sir Brian Follett and Michael Paulson-Ellis, September 2001.

- Ensure legislation relating to research is followed within the organisation.
- Require that no research study with human participants for whom the organisation is responsible (or their organs, tissue or data), begins until
 - a sponsor has confirmed it has taken responsibility;
 - the proposed research has a favourable ethical opinion (and if the study is a trial of a medicine, until there is a clinical trial authorisation); and
 - a person authorised to do so has given written permission on behalf of the organisation providing care.²⁹
- Ensure written agreements are in place about responsibilities for all research involving an external partner, funder and/or sponsor, including agreement with the university or other employer on supervision of student research.
- Maintain links with clinical governance and/or best value processes.
- Ensure researchers with no contractual relationship with any NHS body³⁰, who are to interact with individuals in a way that directly affects the quality of their care, hold honorary NHS contracts, and that there is clear accountability and understanding of responsibilities.
- Put and keep in place systems to identify and learn from errors or failures associated with any research undertaken through or within the organisation.
- Ensure that significant lessons learnt from errors or complaints and from internal enquiries are communicated to funders, sponsors and other partners.
- Ensure that adverse incidents in the context of research are reported to the National Patient Safety Agency in line with the standard procedures of the organisation; or to the systems for reporting adverse events in social care.
- Permit and assist with monitoring, audit or inspection by relevant authorities.

²⁹ See section 4.4.

³⁰ Researchers have a contractual relationship with an NHS body either when they are employees or when they are contracted to provide NHS services, for example as independent practitioners. Research governance does not require each health and social care organisation to issue a separate honorary contract. When a researcher already has a suitable contractual relationship (which can be a relevant honorary contract), health and social care providers may consider giving permission for research on the same terms.

3.11 RESPONSIBILITIES OF CARE PROFESSIONALS

- 3.11.1 Health and social care staff retain responsibility for the care of their patients or service users, when they participate in research within the NHS.
- 3.11.2 Before agreeing that the research team may approach their patients or service users and carers, care professionals should satisfy themselves that the chief investigator has the permission of the appropriate authorities within their organisation or agency. Before enrolling patients in a clinical study, NHS staff should look for evidence that the study has the ethical and regulatory approval it needs. They should then take care to follow the currently approved version of the protocol.

3.12 RESPONSIBILITIES RELATING TO RESEARCH ETHICS COMMITTEES

- 3.12.1 No research study within the NHS involving individuals, their organs, tissue or data may begin until it has a favourable opinion from a research ethics committee.
- 3.12.2 From 2004, the United Kingdom Ethics Committee Authority has been responsible for recognising ethics committees to review clinical trials under the Medicines for Human Use (Clinical Trials) Regulations 2004. The Human Tissue Act 2004 and the Mental Capacity Act 2005 will also require ethical review by an appropriate body, normally a research ethics committee.
- 3.12.3 The NHS is responsible for establishing, supporting and monitoring NHS Research Ethics Committees (RECs).³¹ Those outside the NHS may also seek the advice of these committees. Social care research involving human participants to whom the NHS has a duty of care (or their organs, tissue or data) must have a favourable opinion from the relevant NHS REC.
- 3.12.4 Research ethics committees are required to be independent when formulating advice on the ethics of the proposed research. Ethics review must be seen to be impartial. NHS RECs are not part of NHS Trust R&D management structures. While they operate within a framework of standards and NHS management, neither the Department of Health nor NHS bodies are entitled to interfere with NHS RECs' decisions. Research ethics committees' appointing authorities must have systems to appoint members and convene them, to seek recognition if the law requires it, and to support them and monitor their performance.

³¹ The duties of NHS bodies in relation to NHS RECs are set out in the good practice guidance *Governance Arrangements for Research Ethics Committees* (Department of Health, 2001).

- 3.12.5** The arrangements for ethics review in social care research are less well developed than in the NHS. There is no system comparable to the long established NHS Research Ethics Committees. Options for ethics review of social care research are under consideration. For the time being, all those involved in social care research should use their best endeavours to ensure it is conducted to high ethical standards and wherever possible draw on existing arrangements for independent ethics review. For example, some funders and sponsors have set up arrangements for ethics review. A number of universities have research ethics committees that advise on the ethics of social care studies. In addition, the Association of Directors of Social Services (ADSS) research group advises the ADSS and individual Directors and Social Services on the ethics, quality and relevance of proposals for multi-site studies. Where these arrangements are not available or appropriate, the sponsor is expected to take responsibility for arranging independent ethics review.
- 3.12.6** Research ethics committees provide an independent opinion. The decision whether or not to give permission for research in a care organisation rests with that organisation. Similarly, Directors of Social Services are responsible for considering permission for social care research conducted within their local authorities. Subject to a favourable ethical opinion, health and social care organisations will not normally withhold permission unless there are local factors that would lead to an unacceptable impact on the quality of health or social care.
- 3.12.7** It is not for research ethics committees or reviewers to give legal advice, nor are they liable for any of their decisions in this respect. It is the researchers and the health or social care organisations³² who have the responsibility not to break the law. If a research ethics committee suspects that a research proposal might contravene the law, it is expected to advise both the chief investigator and the appropriate authority. Then the chief investigator and the organisation will need to seek legal advice. The same applies to those undertaking ethics review of social care research.
- 3.12.8** Research ethics committees require researchers working in the NHS to keep them informed of the progress of a study. The committees are responsible for reviewing their advice on the ethical acceptability of a study in the light of such information. The chief investigator and his or her employer, the sponsor and the care organisation are responsible for ensuring that a study follows the agreed protocol, and for monitoring and reporting on its progress.³³

³² and the sponsor, for clinical trials involving medicines.

³³ For clinical trials of medicines, sponsors have a legal duty to notify the ethics committee and the licensing authority of adverse events, a change to the design of the trial, and the conclusion of the trial.

4 DELIVERY SYSTEMS

- 4.1 Organisations conducting, sponsoring, funding or hosting health and social care research must have systems to ensure that they and their staff understand and follow the standards and good practice set out in this framework.
- 4.2 They must have access to independent expert review that enables the main funder and the sponsor to be satisfied of the scientific and ethical standing of the work, its strategic relevance and value for money. This review must be proportionate to the scale and complexity of each research proposal.
- 4.3 Sponsors must be satisfied there are arrangements to:
- ensure each study is conducted according to the current agreed protocol;
 - monitor and report on its general progress; and
 - require written agreement on behalf of the sponsor to any modifications to the protocol or proposal (and, if necessary, ethical and regulatory approval).
- One of the organisations involved in the research will normally manage these arrangements. The sponsor must satisfy itself that a suitable organisation has accepted this responsibility.
- 4.4 Health and social care providers must have systems that ensure they are aware of research conducted in or through their organisation, whether or not it is externally funded. No study should begin until a person with authority to do so has given written permission³⁴ on behalf of the care organisation. Health and social care organisations are expected to manage risk, minimise bureaucratic process and facilitate high quality research. They are not normally expected to withhold permission when a sponsor offers reasonable assurances that arrangements to carry out the responsibilities set out in this framework. The Department of Health will lead work on national systems to enable health and social care providers to decide promptly that a study is ready to begin.
- 4.5 Primary care trusts are responsible for providing a safe system of care. This responsibility includes research involving NHS patients and anyone else to whom they have a duty of care.

³⁴ *NHS permission for R&D involving NHS patients* (DH, 2004) explains the purpose of this permission.

- 4.6 Organisations commissioning or providing health and social care should normally expect to be kept informed of any study involving their staff, contractors or independent practitioners. However, they do not have responsibility for private research that is clearly separate from the health or social care provided on behalf of the NHS. That is, when:
- the study is clearly undertaken in a private capacity,
 - the research ethics committee is fully aware of the circumstances and
 - participants understand the NHS accepts no liability.
- 4.7 Care providers may take on the sponsor's responsibilities if they have systems to discharge them. It is acceptable for an individual employee to be a sponsor, only with the written permission of that person's employer.³⁵
- 4.8 Nothing in this research governance framework is intended to transfer the legal duties of health and social care organisations to sponsors or to others. Whoever takes on sponsorship, if a study affects a health or social care organisation's duties, it remains that organisation's responsibility to satisfy itself that there are systems to conduct the study to appropriate scientific and ethical standards.
- 4.9 The Department of Health, the Association of the British Pharmaceutical Industry (ABPI) and the Association of the British Healthcare Industries (ABHI) recommend the use of a model clinical trials agreement that has been developed and published jointly.
- 4.10 Research ethics committees and reviewers should have systems to identify, record and address conflicts of interest that may compromise, or appear to compromise, the independence of their advice. They must also have systems to record their decisions and the reasons for them, and to record operational details of their meetings and handling of applications. References to the law and guidance on this are in the Annex. From 2005, the National Patient Safety Agency became responsible for the Central Office for Research Ethics Committees, providing advice, assistance and national systems to support the work of research ethics committees.

³⁵ For clinical trials of medicines, it is within the law for an individual to be the sponsor. Employers should ensure that, if their employees take on sponsorship, there is a system to record whether the employee has permission to do so as a private individual or is authorised to do so on behalf of the employer. Health and social care organisations should authorise their employees to take on sponsorship, only if there are arrangements to perform the functions in the Medicines for Human Use (Clinical Trials) Regulations 2004.

- 4.11 Delivery systems should be designed to facilitate adherence to requirements and to detect failures, whether such failures arise by intent or oversight. These systems should include a risk-based programme of routine and random monitoring and audit. They should require, facilitate and support reporting of critical incidents, near-misses, systems failures and misconduct either by self-reporting or whistle-blowing.
- 4.12 The Department of Health will work with key stakeholders to develop and issue explanatory material from time to time to help organisations discharge their responsibilities for research governance effectively and efficiently. This will particularly be the case for areas of health and social care where the systems for research governance are less well established. The material will cover systems in individual organisations as well as systems for agreeing and discharging responsibilities between two or more organisations, eg a care provider and a university, or a number of care providers in a multi-centre study.
- 4.13 The Department of Health will work with NHS care providers to ensure that they understand their legal and other responsibilities, have systems to discharge them, and take account of relevant guidance. Arrangements for social care will be developed as part of the implementation of the quality framework outlined in *A Quality Framework for Social Care*.
- 4.14 Research governance depends critically on research workers' and research managers' understanding their responsibilities and having the skills to discharge them. The Department of Health will work with other research funders and universities to promote the coverage of research governance in relevant degree courses and continuing education.
- 4.15 There is much good practice in research and there are many opportunities for individuals and organisations to learn from one another. The Department of Health promotes the development of learning networks to support this. The NHS R&D Forum is a good example, as is the Social Services Research Group.

5 MONITORING, INSPECTION AND FAILURES

- 5.1 Organisations and individuals are expected to be able to
- demonstrate adherence to this framework,
 - reassure patients, service users, carers, and care professionals of the quality of their services, and
 - assure their reputation in high quality research and care.
- 5.2 There are powerful incentives to adhere to the principles, requirements and standards of good practice set out in the framework. These include the law, the duty of care in the NHS and social care, and the high professional and ethical standards that most care professionals and researchers uphold. Mechanisms to monitor the quality of clinical work, such as inspection, audit, risk management and staff appraisal, can assist in the monitoring of research governance. Coherent systems are needed to monitor performance, to identify best practice and shortfalls, to enhance public confidence and help to prevent adverse events. It is an offence not to comply with the law for clinical trials involving medicines. For other research, those involved may be liable under common law if they are negligent. The Department of Health will work with its partners to develop coherent systems for monitoring research governance and addressing shortcomings.
- 5.3 Arrangements will be established to work with and through structures that already exist or are being developed in health and social care, government departments, research councils, universities and charities to promote and monitor quality. These arrangements will monitor the extent to which the standards set out in this framework are being followed by:
- organisations undertaking sponsorship responsibilities (including the Department of Health);
 - health and social care organisations participating in research;
 - universities and other organisations employing researchers;
 - other organisations on which this framework depends.

- 5.4 The Department of Health maintains a public list of sponsors of health and social care research. Organisations are listed after providing assurances that they are willing and able to take on sponsorship. Organisations not on the list may decide to take on sponsorship of particular studies.
- 5.5 Research governance is one of a set of quality systems for health and social care. Reporting, inspection and review supports organisations' systems for meeting standards and managing risk. The National Patient Safety Agency maintains a national system for reporting adverse events in the NHS. There are systems for reporting adverse events in social care. Clinical trials of medicines require authorisation by the Medicines and Healthcare products Regulatory Agency. The Agency operates a system of Good Clinical Practice and Good Manufacturing Practice inspections. They can involve trial sites, units manufacturing investigational medicinal products, and sponsors. Similar arrangements apply to medical devices.
- 5.6 From 2005, research governance is one of the core standards all organisations should achieve in delivering NHS care. Health care organisations which either lead or participate in research should have systems to ensure that the principles and requirements of this research governance framework are consistently applied. They are to measure compliance using self-assessment tools.
- 5.7 Failure in NHS organisations to comply with this framework will be addressed through the normal lines of accountability and performance management. The Healthcare Commission will be responsible for an assessment framework including reviews and inspections of NHS service providers and others providing health care for which NHS bodies and service providers have responsibility. If an organisation fails to satisfy the Commission that it meets a core standard such as research governance, it is expected to develop proposals for improvement in negotiation with its Strategic Health Authority. The Commission can recommend to the Secretary of State, or in the case of a Foundation Trust, to Monitor, the Independent Regulator, that they take special measures in relation to any significant failings.
- 5.8 Failures on the part of staff in the Department of Health or the NHS, or on the part of relevant staff within Councils with Social Services Responsibilities, to meet responsibilities relating to this framework will be addressed through the normal management channels and disciplinary procedures. It is the responsibility of other organisations to have appropriate systems to address failures by their staff. University employees with NHS honorary contracts may have their contracts withdrawn, subject to a joint NHS/university investigation.

- 5.9 In the case of misconduct, professional groups are subject to disciplinary action by their professional bodies. The Council for the Regulation of Health Care Professionals will promote best practice and co-operation between regulatory bodies. For example, doctors are responsible to the General Medical Council for their professional conduct as researchers as well as clinicians. Similarly, nurses, midwives and health visitors are responsible to the Nursing and Midwifery Council. Members of 13 other health professions are responsible to the Health Professions Council for their professional conduct as researchers as well as clinicians. Misconduct by social care professionals will be one of the responsibilities of the General Social Care Council.
- 5.10 There is public and professional concern about research misconduct and fraud, though its extent is unknown. The NHS Counter Fraud and Security Management Services have overall responsibility for all work to counter fraud and corruption within the NHS. Controls assurance systems under *Standards for Better Health*³⁶ will enable health and social care organisations to check whether there are mechanisms to detect and investigate possible fraud, and to take appropriate action. Health and social care organisations should seek assurances that universities and any other organisations with whom they develop local partnerships have systems for detecting, investigating and addressing fraud by their employees. In 2005, Universities UK aim to establish a UK Panel for Research Integrity in Health and Biomedical Sciences. It will provide advice on maintaining high standards of scientific integrity, and support to those investigating allegations of research misconduct. Its advice and support will be available to employers of researchers including health and social care organisations. The Department of Health will continue to work with universities and others on measures to promote integrity in research.
- 5.11 The Department of Health looks to those with responsibility for other organisations to address any shortcomings in them. Department of Health and NHS funds for health and social care research will be allocated to those competent to manage them and the work they support.

³⁶ *Standards for Better Health, published with National Standards, Local Action* (DH, 2004), set out the level of quality all organisations providing NHS care will be expected to meet across the NHS in England.

ANNEX

The Annex can be found on the Department of Health's website: www.dh.gov.uk



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