

**SCOTTISH EXECUTIVE HEALTH
DEPARTMENT**

**RESEARCH GOVERNANCE
FRAMEWORK**

for

HEALTH AND COMMUNITY CARE

Second Edition, 2006

Preface to the Second Edition, 2006

This update of the Research Governance Framework for Health and Community Care in Scotland takes account of a number of developments that have taken place since the framework was first published in 2001. Regulations on clinical trials involving medicines took effect in 2004. The regulations clarify specific legal duties of sponsors, investigators and others in such clinical trials. The change in the law stimulated wide debate on good practice and regulatory process in collaborative trials. The lessons drawn are visible throughout this edition and recognise the need to achieve a proper balance by safeguarding the rights of patients involved in clinical trials while avoiding a disproportionate impact on those who carry them out. Related changes in the sponsor responsibilities for other research are also reflected in this edition. There are also revisions to take account of changes in the organisation of NHS research ethics committees.

We hope that these changes combined with further clarification of a number of details will provide a solid base on which to move forward, encouraging greater public confidence in research and further investment and activity.

Chief Scientist Office
Scottish Executive Health Department

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RESEARCH GOVERNANCE FRAMEWORK

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Research Governance

- ❖ Sets out principles, requirements and standards
- ❖ Defines mechanisms to deliver them
- ❖ Describes monitoring and assessment arrangements
- ❖ Improves research quality and safeguards the public by:
 - enhancing ethical 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 all managers and staff, in all professional groups, no matter how senior or junior
- ❖ Is for those working in all health and community care environments, including:
 - primary care
 - secondary care
 - tertiary care
 - community care
 - public health

1. PURPOSE AND SCOPE

- 1.1 The Scottish Executive is committed to enhancing the contribution of research to health and community care, and the partnership between services and science. Research is essential to the successful promotion and protection of health and well-being and also to modern, effective health and community 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 therefore essential to ensure that the public can have confidence in, and benefit from, quality research in health and community 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 community care. The principles underpinning the framework apply to all research which relates to the responsibilities of the Minister for Health and Community Care. That is, research concerned with the protection and promotion of public health, research undertaken in or by the Scottish Executive Health Department, (SEHD), its non-Departmental Public Bodies and the NHS, and community care research. Within this context, it applies to clinical and non-clinical research; research undertaken by NHS or community care staff using the resources of health and community care organisations; and any research undertaken by industry, charities, research councils and universities within the health and community care systems that might have an impact on the quality of those services.
- 1.3 This framework does not apply to research concerned with the delivery of local authority services outwith the Minister for Health and Community Care's responsibilities unless they are carried out in NHS settings or in collaboration with NHS care providers. In addition, the framework does not apply to research in the Scottish Prison Service except where this involves medical treatment or the provision of other health services. Although this work is governed by separate arrangements, the principles underpinning this framework should be applied whenever possible.
- 1.4 Important differences between health and community care research mean that the precise mechanisms by which relevant standards and requirements are achieved will differ. Compared with much research in the NHS, research in community care differs in nature, scale, volume and funding as well as in the mix of stakeholders, the organisational context and the range of academic disciplines. This framework focuses on requirements and standards, delivery mechanisms, and arrangements to monitor quality for health research. It is expected that organisations involved in community care research will develop their own mechanisms for the delivery, monitoring and assessment of research which reflect the principles set out in this framework, are proportionate to the risk involved and have regard to existing codes of good practice. The Scottish Executive is reviewing and improving existing ethical assurance processes for social research it commissions or undertakes to support Ministers and policy development taking account of the framework principles.
- 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 checklist of responsibilities in Section 3 are there to help everyone reach agreement on arrangements that are proportionate to risk, and for

health research to be 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 Minister for Health and Community Care 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 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, 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 community care generate and draw upon 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 methods.¹ 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 community care set out standards and systems for assuring the quality of innovative work in non-research contexts.
- 1.11 Inquiries into adverse incidents relating to research have criticised a lack of clarity about responsibility and accountability. 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. Listed are some of the individuals and organisations involved in health and community care research:
 - ◆ The Public
 - ◆ Research workers
 - ◆ NHS staff
 - ◆ Universities
 - ◆ Students and their supervisors
 - ◆ Research ethic committees
 - ◆ Non-commercial research funders
 - ◆ Health and community care professionals
 - ◆ Health and community care organisations
 - ◆ The pharmaceutical and other industries

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

◆ Local authorities

1.12 Achieving high quality in research depends on co-operation between all those involved. SEHD 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 community care research.

2. STANDARDS

2.1 Clinical governance aims continually to improve the overall standards of clinical care in the NHS and to reduce unacceptable variations in clinical practice. Clinical Governance and Risk Management (CGRM) standards² were launched by Quality Improvement Scotland (QIS) in 2005. The performance of NHS Boards and Special Health Boards will be assessed against these standards which include compliance with research governance.

2.2 Health 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 six domains:

- ◆ ethics
- ◆ science
- ◆ information
- ◆ health and safety
- ◆ finance
- ◆ quality research culture.

2.3 Each domain has been grouped as follows:

- ◆ requirements in legislation and regulations
- ◆ standards required by SEHD
- ◆ other established principles of good practice from recognised international and national authorities and professional organisations.

2.4 The Chief Scientist Office website will provide regular updates of detail. The following sections set out principles in each domain.

Ethics

2.5 The dignity, rights, safety and well-being of participants must be the primary consideration in any research study.

2.6 SEHD requires that all health 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 Informed consent is at the heart of ethical research. Most studies involving individuals must have appropriate arrangements for obtaining consent and the NHS 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. For example, The Adults with Incapacity (Scotland) Act 2000 provides safeguards for adults who lack

² Clinical Governance and Risk Management Standards (QIS, 2005)

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 The NHS Code of Practice on Protecting Patient Confidentiality published in August 2003 provides guidance on obtaining consent. NHS HDL (2003)37 on The Use of Personal Health Information in NHSScotland to Support Patient Care provides further information.

capacity to consent to research.⁵ 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.

- 2.7 Care is also needed when research involves tissue or organs. The consent of the person concerned or the relatives of the deceased must always be obtained. It must be recognised that 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.
- 2.8 The appropriate use and protection of patient data are also key. All those involved in health research must be aware of their legal and ethical duties in this respect. Particular attention must be given to systems for ensuring confidentiality of personal information and to the security of those systems.
- 2.9 It is essential that health research reflects the practicalities of care delivery. To that end, relevant service users and carers or their representative groups should be involved wherever possible in the design, conduct, analysis and reporting of research.
- 2.10 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.
- 2.11 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 benefit⁶. Risks, pain or discomfort must always be kept to a minimum and explained clearly both to the relevant ethics committee and to participants. It must always be explained whether there are arrangements for compensation in the unlikely event of non-negligent harm.
- 2.12 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. Where animal use is unavoidable, there are strict controls,

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 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.

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 Home Office requirements.

Science

- 2.13 All existing sources of evidence, especially systematic reviews, must be considered carefully before undertaking health research. Research which duplicates other work unnecessarily or which is not of sufficient quality to contribute something useful to existing knowledge is unethical. Every proposal for health 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.
- 2.14 The Medicines for Human Use (Clinical trials) Regulations 2004⁷ 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 health research involving patients, not just clinical trials.⁸
- 2.15 Special regulations govern the use of human embryos, the release of genetically modified organisms and food or food processes and further information on these areas should be sought where appropriate.
- 2.16 Data collected in the course of health 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.

Information

- 2.17 Health 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 conducted⁹ and on the findings of the research - positive or negative - once these have been subjected to appropriate scientific review. Information

⁷ The Medicines for Human Use (Clinical Trials) Regulations transposed Directive 2001/20/EC into UK law.

⁸ The Medical Research Council (MRC) 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).

⁹ There is an international consensus that, with certain exemptions, information identifying a clinical trial of a treatment should be available on a public register from the time the first participant is recruited.

should be presented in a format understandable to the public. Reports need to be comprehensible and take language and other needs into account.

- 2.18 Some advances in healthcare 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.
- 2.19 All those conducting health research must open their work to critical review through the accepted scientific and professional channels. Once established, findings must be made accessible to those participating¹⁰ 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.

Health and Safety

- 2.20 Health 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.

Finance

- 2.21 Financial probity and compliance with the law and with the rules laid down by the Scottish Executive and H M Treasury for the use of public funds are as important in research as in any other area. Organisations employing researchers must be in a position to compensate anyone harmed by their negligence. If an organisation offers to compensate participants in the event of non-negligent harm, it must be in a position to do so. Consideration must be given to the exploitation of intellectual property rights.¹¹

Quality research culture

- 2.22 Some of the principles and requirements applying to health research are clear-cut but 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.

- 2.23 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

¹⁰ Including the relatives of deceased patients who have consented to the use of organs or tissue in the research.

¹¹ Guidance for NHSScotland is set out in the document "A Framework and Guidance on the Management of Intellectual Property in the NHSScotland" (HDL (2004) 9).

- ◆ honesty
- ◆ accountability
- ◆ openness
- ◆ clear and supportive management

2.24 Box A illustrates how research is managed in a health organisation with a quality research culture. A quality research culture is essential for proper governance of health research.

BOX A: FEATURES OF A QUALITY RESEARCH CULTURE IN THE NHS

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.
- 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

- To safeguard the dignity, rights, safety and well-being of participants 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.
- 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.
- 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. This 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 who may need information in different formats because of a disability e.g. 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 which 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.

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 laid down by the Scottish Executive and H M Treasury. It complies with all audit required by external funders or sponsors and has systems in place 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 ACCOUNTABILITIES

General

- 3.1 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.
- 3.2 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.

Agreements

- 3.3 A complex array of organisations and individuals may be involved in a health research study. It is essential that clear agreements describing allocation of responsibilities and rights are reached, documented and enacted.
- 3.4 Many agreements will relate to individual studies. Organisations that collaborate on a range of research work are encouraged to develop and document framework agreements to facilitate the agreement of responsibilities for specific studies; for example:
 - ◆ NHS organisations who work together regularly on research, whether or not in a formal network;
 - ◆ Universities and NHS organisations, primary care practices and research networks that work together regularly on research;
 - ◆ local authorities and/or other community care providers, NHS organisations, and primary care practices that work together regularly on research whether or not in a formal research network.
- 3.5 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 the 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 refer to the protocol.

Specific Responsibilities

- 3.6 Box B describes the terms used in this research governance framework for the main people and organisations involved in a health research study.
- 3.7 The key responsibilities of the people and organisations accountable for the proper conduct of a health study are summarised in Box C. Box D illustrates the responsibilities with a scenario. The remainder of this section sets out these responsibilities in more detail.

BOX B MAIN PEOPLE AND ORGANISATIONS INVOLVED IN A HEALTH RESEARCH STUDY

Participant - patient, service user, and 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).

Researchers - those conducting the study.

Investigator - the person responsible, individually or as the 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.

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.

Principal Investigator – the leader responsible for a team of individuals conducting a study at a site.

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.

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).

Employing Organisation - the 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.

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

Responsible Care Professional - doctor, nurse or other practitioner formally responsible for the care of participants while they are taking part in 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 committee must be one recognised by the United Kingdom Ethics Committee Authority.

BOX C SUMMARY OF KEY RESPONSIBILITIES OF PEOPLE AND ORGANISATIONS ACCOUNTABLE FOR THE PROPER CONDUCT OF A HEALTH RESEARCH STUDY

Chief Investigator, Investigators, other Researchers

- 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.

See 3.10, 3.11 to 3.13

Main Funder

- 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.

See 3.14 to 3.18

Sponsor

- Confirming that everything is ready for the research to begin:
 - 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 medicines, seeking a clinical trial authorisation and making arrangements for investigational medicinal products. (The Medicines for Human Use (Clinical Trials) Regulations 2004 specify the responsibilities that have to be taken by or on behalf of sponsors of trials involving medicines).
- 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.

See 3.19 to 3.24

BOX C SUMMARY OF KEY RESPONSIBILITIES OF PEOPLE AND ORGANISATIONS ACCOUNTABLE FOR THE PROPER CONDUCT OF A HEALTH RESEARCH STUDY (CONTINUED)

Employing Organisation

- 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.

See 3.25 to 3.28

Organisation Providing Care/ Responsible Care Professional

- 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.

See 3.29 to 3.34

BOX D SPECIFIC RESPONSIBILITIES OF KEY PEOPLE INVOLVED IN HEALTH RESEARCH

SCENARIO: WHO IS RESPONSIBLE FOR WHAT? SOME QUESTIONS AND ANSWERS

The 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. The research is taking place in general practices. The Medicines and Healthcare products Regulatory Agency (MHRA) has agreed that the university and the relevant NHS Board 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.

PATIENT

Q: I did tell my GP that I might be interested in joining the study, but that does not commit me definitely, does it?

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: You can take away this patient information leaflet to study, and 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 advise her immediately if we detect any 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.

G.P.

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

A: The university and NHS Board are together sponsoring the study. The protocol names the sponsors' contact points. The scientific design went through the MRC's 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 must ensure you are satisfied with these arrangements and discuss them with the chief investigator if you are not.

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

A: The chief investigator is responsible for ensuring that you and every other person involved in the study is 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 this, you should contact the chief investigator. If you are not satisfied, you should inform the sponsor's representative.

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.

BOX D SPECIFIC RESPONSIBILITIES OF KEY PEOPLE INVOLVED IN RESEARCH (CONTINUED)

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

A: Please talk to the chief investigator. A better understanding of the consent process could resolve the issues. Perhaps communication with your patients could be improved, for example by revising the patient information leaflet. If there are still problems you are free to withdraw.

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. The sponsor's 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 the Central Office for Research Ethics Committees (COREC) website. You need a positive ethics committee opinion as well as a Clinical Trial Authorisation before you can start the trial.

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 that 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 that 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, whom should I talk to?

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.

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

A: You should discuss this with the Trial Steering Committee. If they agree, you will 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. 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.

Responsibilities of Participants

- 3.8 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 Scotland offers the likelihood of real benefits either to those who participate, or to those who use services subsequently, or to both. Anyone using health services should give serious consideration to becoming involved in developing or undertaking research studies.
- 3.9 Researchers are responsible for selecting means of communication that ensure that 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.

Responsibilities of Researchers

- 3.10 Researchers bear the primary 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.

Responsibilities of Investigators and the Chief Investigator

- 3.11 A senior individual must be designated as the chief investigator for the research. 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. They are 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.
- 3.12 Chief investigators must have suitable experience and expertise in the design and conduct of research¹² 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.
- 3.13 It is the chief investigator's responsibility to ensure that:

¹² For clinical trials involving medicines, the chief investigator and other investigators must be authorised healthcare professionals as defined in the Medicines for Human Use (Clinical Trials) Regulations 2004.

- 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;
- Controlled trials are registered and for clinical trials involving medicines, the research follows any conditions imposed by the licensing authority;
- 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 other 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 their 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;
- 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;
- 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;
- Unless urgent safety measures are necessary,¹³ the research follows the protocol or proposal agreed by the relevant ethics committee and by the sponsor¹⁴;
- 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;¹⁵
- Procedures are kept in place to ensure collection of high quality, accurate data and the integrity and confidentiality of data during processing and storage¹⁶;
- Arrangements are made for the appropriate archiving of data when the research has finished and to make it accessible;

¹³ Investigators in clinical trials involving medicines have to report serious adverse events immediately.

¹⁴ 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).

¹⁵ Also, for clinical trials involving medicines, to the licensing authority.

¹⁶ 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.

- 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;
- Once established, findings from the work are disseminated promptly and fed back as appropriate to participants;
- The chief investigator accepts a key role in detecting and preventing scientific misconduct by adopting the role of guarantor on published outputs;
- 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;
- All data and documentation associated with the study are available at the request of the inspection and auditing authorities.

Responsibilities of Research Funders

- 3.14 Organisations that fund health research have a responsibility for ensuring that the work is a proper use of the funds they control and provides value for money.
- 3.15 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.¹⁷
- 3.16 The main research funder is normally the organisation that makes the arrangements for independent expert review to assess the quality of the research proposed; the experience and expertise of the chief investigator and other key researchers involved; 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 the independent expert review, it should expect the sponsor to arrange for it before taking on responsibility for the research, 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.
- 3.17 Funders are expected to provide assistance to any enquiry, audit or investigation related to the funded work.
- 3.18 Funders are expected to make their funding conditional on identifying a sponsor. Organisations wishing to fund research which requires the collaboration of the NHS in Scotland will either take on sponsorship themselves, or collaborate with another organisation which is willing and able to do so.

¹⁷ 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.

Responsibilities of the Sponsor

- 3.19 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 study¹⁸. For any research that takes place in the context of the NHS in Scotland, 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 healthcare, or the main funder. If the sponsor is outside the United Kingdom, it must have a legal representative in the United Kingdom.¹⁹ For any health 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.
- 3.20 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 that arrangements are in place allocating responsibilities for the management, monitoring and reporting of the research. 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.
- 3.21 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 organisation employing the chief investigator 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.
- 3.22 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 their own audit processes.
- 3.23 When no external sponsor takes on responsibility for it, a study may proceed only if a care organisation takes on sponsorship. For example, an NHS organisation may be willing and able to act as the sponsor for research which does not have an

¹⁸ For clinical trials involving medicines, the sponsor is defined as the person (e.g. 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.

¹⁹ The Regulations require a sponsor to be established, or have a legal representative, in the European Community. Neither of them need to be established in the United Kingdom.

external sponsor. When research is undertaken 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.

3.24 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 that the research proposal is worthwhile, of high scientific quality and good value for money;
- An appropriate ethics committee 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 if significant developments²⁰ occur as the study progresses, whether in relation to the safety of individuals or to scientific direction²¹;
- Agreement has been reached about compensation in the event of harm to research participants²² and if any organisation, or the sponsor itself, offers compensation without proof of negligence, it has made the necessary financial arrangements;
- 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.

²⁰ 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.

²¹ 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.

²² 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.

Responsibilities of Universities and others Employing Researchers

- 3.25 Employers of staff involved in 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 will involve 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.
- 3.26 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 reporting²³.
- 3.27 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.
- 3.28 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;

²³ 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.

- 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.

Responsibilities of Organisations Providing Care

- 3.29 It is the responsibility of organisations providing healthcare in Scotland to be aware of all research undertaken in their organisation, or involving participants, organs, tissue or data obtained through the organisation. Care providers remain responsible for the quality of all aspects of the care of their patients or service users and carers, whether or not they are involved in research and whoever conducts or funds that research. Chief Executives of NHS organisations are accountable for the quality of care and for the environment in which it is provided under the Duty of Care. 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 activity is presented as research only if it is managed as research within this framework.
- 3.30 Organisations providing healthcare are responsible for satisfying themselves that there are 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 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.
- 3.31 Academic staff (university/college medical, nursing, and allied health professionals and other research workers) who, in the course of their NHS research duties, interact with individuals in a way which has a direct bearing on the quality of their care should hold an NHS honorary contract.²⁴ When universities and healthcare organisations are both involved in employing clinical academic staff, they are expected to make joint arrangements for appointment, supervision and appraisal.
- 3.32 The main responsibilities of organisations providing healthcare 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;
 - Be aware and maintain a record of all research work undertaken through or within the organisation including research undertaken by students as part of their training;
 - Ensure patients or service users and carers are provided with information on any research that may affect their care;

²⁴ 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, academic staff with honorary contracts (as defined in paragraph 3.31) and those conducting the study. Guidance for the NHSScotland can be found in the document "Guidance Note on Research Governance and Honorary Contracts", (Health Department, March, 2004).

- Be aware of current legislation relating to research and ensure that it is implemented and 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, that there is a clinical trial authorisation); and a person authorised to do so has given written permission on behalf of the organisation providing care²⁵;
- Ensure that 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 the necessary links with clinical governance and/or best value processes;
- Ensure that NHS honorary contracts are issued where appropriate²⁶. There should be 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 in line with the standard procedures of the organisation;
- Permit and assist with any monitoring, auditing or inspection by relevant authorities.

Responsibilities of Care Professionals

- 3.33 Healthcare staff retain responsibility for the care of their patients or service users when they are participating in research within the NHS.
- 3.34 Before agreeing to their patients or service users and carers being approached by the research team, 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.

Responsibilities Relating to Research Ethics Committees

- 3.35 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.
- 3.36 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.
- 3.37 The NHS is responsible for establishing, supporting and monitoring NHS research ethics committees (RECs). The duties of NHS bodies in relation to NHS RECs are set out in the good practice guidance *Governance Arrangements for Research Ethics Committees in Scotland* (SEHD, 2001). Those outside the NHS may also

²⁵ See section 4.4.

²⁶ See footnote 24.

seek the advice of these committees. Community 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.

- 3.38 RECs are required to be independent when formulating advice on the ethics of the proposed research. Ethics review must be seen to be impartial. Whilst operating within a framework of standards and NHS management, neither SEHD nor NHS bodies are entitled to interfere with NHS RECs' decisions. RECs' appointing authorities must have systems in place to appoint members and convene them, to seek recognition if the law requires it, and to support them and monitor their performance.
- 3.39 RECs provide an independent opinion. The decision whether or not to give permission for research in a care organisation rests with that organisation. Healthcare organisations will not normally withhold permission provided that a sponsor has been identified, the ethical opinion is favourable, the agreements for allocation of responsibilities or indemnity and/or insurance are acceptable to the organisation, and conducting the research will not conflict with service delivery in some way due to local issues that might not have been considered by the ethics approval or sponsor.
- 3.40 It is not for RECs or reviewers to give legal advice, nor are they liable for any of their opinions in this respect. It is the researchers and the healthcare organisations²⁷ who have the responsibility not to break the law. If a REC 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.
- 3.41 RECs 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.²⁸

²⁷ and the sponsor, for clinical trials involving medicines.

²⁸ For clinical trials of medicines, sponsors have a legal duty to notify the ethics committee and the licensing authority if there are adverse events, a change to the design of the trial, and the conclusion of the trial.

4. ACHIEVING GOVERNANCE

- 4.1 Organisations conducting, sponsoring, funding or hosting health research must have systems to ensure that they and their staff understand and follow the standards and good practice set out in this framework.

Delivery

- 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 appropriate to the scale and complexity of each research proposal.
- 4.3 Sponsors must be satisfied there are arrangements to ensure that 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 Healthcare 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 permission²⁹ on behalf of the care organisation. Healthcare 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 there are arrangements to carry out the responsibilities set out in this framework.
- 4.5 Healthcare 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.³⁰
- 4.6 Nothing in this research governance framework is intended to transfer the legal duties of healthcare organisations to sponsors or to others. Whoever takes on sponsorship, if a study affects a healthcare 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.
- 4.7 Healthcare organisations are responsible for providing a safe system of care and should normally expect to be kept informed of any study involving their staff, contractors or independent practitioners. However, they do not have responsibility

²⁹ Additional guidance can be found in "Research Governance: NHS Approval for R&D Involving NHS Patients" (SEHD, 2004).

³⁰ For clinical trials of medicines, it is within the law for an individual to be the sponsor (further guidance on this can be found at www.ct-toolkit.ac.uk/db/documents/sponsorship.pdf). 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. Healthcare 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.

for private research that is clearly separate from the healthcare provided on behalf of the NHS. That is when the study is clearly undertaken in a private capacity, the REC is fully aware of the circumstances and participants understand the NHS accepts no liability.

- 4.8 RECs 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 in place to record their decisions and the reasons for them, and to record operational details of their meetings and handling of applications.
- 4.9 Delivery systems should be designed to facilitate adherence to requirements, and to detect failures whether such failures arise by intent or oversight. Such 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.
- 4.10 SEHD 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.
- 4.11 SEHD 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.
- 4.12 Research governance depends critically on research workers and research managers understanding their responsibilities and having the skills to discharge them. SEHD will work with other relevant parties to help to promote the coverage of research governance.

Adherence to the Framework

- 4.13 Organisations and individuals are expected to be ready to demonstrate adherence to this framework, reassure patients, service users and care professionals of the quality of their services and assure their reputation in high quality research and care.
- 4.14 There are powerful incentives to adhere to the principles, requirements and standards of good practice set out in the framework. These include the law, duties of 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. SEHD will work with its partners to develop coherent systems for monitoring research governance and addressing shortcomings.

- 4.15 Arrangements will be established to work with and through structures which already exist or are being developed in healthcare, 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 bodies who undertake the responsibilities of sponsors of health research, healthcare organisations participating in research, universities and other organisations employing researchers, and other organisations on which this framework depends.
- 4.16 Research governance is one of a set of quality systems for healthcare. Reporting, inspection and review supports organisations' systems for meeting standards and managing risk. 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 which can involve trial sites, units manufacturing investigational medicinal products, and sponsors. Similar arrangements apply to medical devices.
- 4.17 Healthcare 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. Failures in NHS organisations to comply with this framework will be addressed through the normal lines of accountability and performance management. NHS QIS will be responsible for reviewing the performance of NHS Boards against clinical governance and risk management standards launched by QIS in 2005. Research governance forms part of these standards and to support the review process, a self assessment tool to measure compliance with research governance will be launched by SEHD in 2006.
- 4.18 Failures on the part of staff in SEHD or the NHS 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.
- 4.19 In the case of misconduct, professional groups are subject to disciplinary action by their professional bodies. The Council for Healthcare Regulatory Excellence 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. State registered practitioners are responsible to the Health Professions Council for their professional conduct as researchers as well as clinicians.
- 4.20 There is public and professional concern about research misconduct and fraud, though its extent is unknown. Monitoring of compliance with research governance will check whether there are mechanisms to detect and investigate possible fraud and to take appropriate action if fraud is found. In addition, healthcare 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. 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 healthcare organisations. SEHD will continue to work with universities and others on measures to promote integrity in research.

4.21 SEHD looks to those with responsibilities for other organisations to address any shortcomings in them. SEHD and NHS funds for health research will be allocated to those competent to manage them and the work they support.

4.22 The Annex to the Research Governance Framework for Health and Social Care in England contains further information on legislative requirements, standards and good practice guidelines applying to research. This can be found on the Department of Health in England's website at:

<http://www.dh.gov.uk/PolicyAndGuidance/ResearchAndDevelopment/fs/en> .

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.