

**RESEARCH GOVERNANCE
FRAMEWORK
FOR
HEALTH AND SOCIAL CARE**



Department of Health, Social Services and Public Safety

December 2006

Preface

This Research Governance Framework for Health and Social Care takes account of a number of developments that have taken place since the framework was issued for consultation in 2002.

Regulations on clinical trials involving medicines took effect in 2004. The regulations clarify specific legal duties of sponsors, investigators and others in such 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.

There are also revisions to take account of changes in the organisation of research ethics committees and changes in the responsibilities for funders and sponsors. Regulations affecting the use of human tissue in research took effect in 2006 and these have again been reflected where relevant.

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.

Research & Development Office
December 2006

<i>Contents</i>		<i>Page No</i>
Preface		1
Abbreviations		3
Section 1	Purpose and Scope	5
Section 2	Standards	11
Section 3	Responsibilities and Accountability	21
Section 4	Achieving Governance	41

<i>List of Illustrations</i>		<i>Page No</i>
Box A	Research Governance	4
Box B	Research or Audit?	8
Figure 1	Research governance framework for Health and Social Care	10
Box C	Protecting Research Participants Rights	15-16
Box D	Standards in a Quality Organisation undertaking Research	19-20
Box E	A-Z of the Main People and Organisations involved in a Health or Social Care Research Study	23-24
Box F	Summary of key responsibilities of people and organisations accountable for the proper conduct of a study	28-29
Box G	Specific responsibilities of key people involved in research	38-40
Box H	Publications	45

Abbreviations

COREC	Central Office for Research Ethics Committees
CSA	Central Services Agency
GaFREC	Governance Arrangements for Research Ethics Committees
HPSS	Health and Personal Social Services
HSS	Health & Social Services
MDA	Medical Devices Agency
MHRA	Medicines and Healthcare products Regulatory Agency
MRC	Medical Research Council
NISCC	Northern Ireland Social Care Council
ORECNI	Office of Research Ethics Committees for Northern Ireland
R&D Office	Research and Development Office for the Health & Personal Social Services
REC	Research Ethics Committee
RGF	Research Governance Framework for Health and Social Care
RQIA	Regulation Quality and Improvement Authority
The Department	The Department of Health, Social Services and Public Safety (DHSSPS)
UKECA	United Kingdom Ethics Committees Authority

BOX A: 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 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 protocols for research
 - 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

Section 1 Purpose and Scope

BACKGROUND

- 1.1 The Department is committed to enhancing the contribution of research to health and social care, and to the partnership between services and science. Research is essential to the successful promotion and protection of health and well-being and to modern and effective health and social care services. At the same time health and social care 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. 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.

A NEW FRAMEWORK

- 1.2 This document sets out a framework for the governance of research conducted by or on behalf of the Health & Personal Social Services (HPSS). The standards in this framework apply to all research undertaken in the HPSS, by, or on behalf of, the Department, or Health & Social Services (HSS) bodies and non-Departmental Public Bodies, that might have an impact on the quality of health and social care services. This includes clinical and non-clinical research, research undertaken by HPSS staff using HPSS resources, and research undertaken by industry, the charities, the research councils and universities within the health and social care systems. In certain circumstances some elements of Research Governance, for example Research Ethics, extend to non-HPSS research activity.
- 1.3 Health and social care organisations should have systems to ensure the principles and requirements of this research governance framework are consistently applied. Health and social care organisations have to take this standard into account in discharging their duty of quality under HPSS (Quality, Improvement and Regulation) (NI) Order 2003.
- 1.4 The aim of this framework is to bring together general principles of good practice including clinical trials involving medicines. That does not mean it imposes the same procedures on all 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. The framework is also offered as a model for the governance of research in areas outside the direct

responsibility of the Minister for Health where poor practice could have a direct impact on the health or wellbeing of the public.

- 1.5 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 restricted to Chief Investigators, managers or to any one professional group. All service and academic staff, no matter how senior or junior, have a role to play in the proper conduct of research. It embraces participants in research and the public in general who can also help to ensure that standards are understood and met.
- 1.6 This framework seeks to promote improvements in research quality across the board. As with clinical and social care governance, research governance aims to bring general performance up to the standard 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.
- 1.7 The framework also aims to prevent poor performance, adverse incidents, research misconduct and fraud, and to ensure that lessons are learned and shared when poor practice is identified. Achievement of these aims will promote good practice, enhance the ethical and scientific quality of research and safeguard the public.

DEFINITION OF RESEARCH

- 1.8 Health and social care services generate and draw upon a wide range of innovative work and ideas from professionals, organisations and the public. Services must promote innovation and its benefits whilst protecting participants from risk and waste. Innovation embraces a much wider range of activities than those managed formally as research. Research has a wide variety of definitions often depending on the circumstances under which it is used.

For the purposes of this document, research is defined as a systematic activity that:

- attempts to answer a clearly defined question
- employs systematic and rigorous methods – including quantitative and/or qualitative paradigms
- leads to generalisable and new knowledge

For an activity to be classified as research it must meet all three qualifying statements.¹ (Guidance on distinguishing between Research and Audit is provided in Box B on page 8.)

¹ Recent work carried out by the Central Office for Research Ethics Committees Consultation E-Group has developed a table to help distinguish between research, clinical audit and service evaluation. This can be accessed at www.corec.org.uk/recs/guidance/docs/Audit_or_Research_table.pdf

ACCOUNTABILITY AND STANDARDS

- 1.9 The guidance on clinical and social care governance sets the framework for putting in place systems for assuring the quality of innovative work in non-research contexts. This document complements that work and sets out the responsibilities and standards that must be applied to work managed within the formal research context.
- 1.10 This research governance framework describes:
- arrangements to define and communicate clear quality standards
 - delivery mechanisms to ensure that these standards are met
 - arrangements to monitor quality and assess adherence to defined standards
- 1.11 Research management processes that support this research governance framework should be put in place in all HPSS organisations, with appropriate reporting arrangements at board level.
- 1.12 Experience from adverse incidents relating to research underlines the need for clearly delineated responsibilities and accountabilities for health and social care research. This is of particular importance given the very wide range of individuals and organisations that can be involved in a single research project. This includes the need for accountability arrangements, which in the case of human organs and tissue are the subject of codes of practice issued by the Human Tissue Authority. The framework set out in this document therefore pays particular attention to clarifying responsibilities and accountabilities for those involved in research.

BOX B: RESEARCH OR AUDIT?

Audit and Research have much in common; they share a rigorous approach to methodology in terms of design, procedure, analysis and interpretation of data. At times, the distinction between Research and Audit can be blurred. However there are a number of major differences and this table is provided to assist in determining what is research (and falls within this Framework) and what is audit. Ultimately the decision into what category a particular project belongs will fall to either an Audit Department or a Research Ethics Committee.

In general:

- Research asks the question "What ought we be doing?" while Audit asks the questions "Are we doing what we ought to?" Or put another way, Research is concerned with discovering the right thing to do; audit is ensuring that it is done right.

Further differences include:

Research	Audit
<ul style="list-style-type: none">● Research is a systematic investigation which aims to increase the sum of knowledge. It usually involves the testing of a hypothesis or theory● Research generates the knowledge that may be tested in Audit● Research is the act of finding the correct thing to do and identifying the most effective form of intervention. This defines best practice● May involve allocating service users to different groups for trials and analysis● May involve the use of a placebo (however it may be defined)● Research may involve a completely new treatment and usually investigates an area where there is no knowledge of the best practice● Research results can be generalised across a wide population● Research requires the co-operation of users and professionals to establish a representative sample so that the results of the research can be generalised● Research results are published universally in order to share the knowledge with a wide user base of professionals● Research has a defined end-point	<ul style="list-style-type: none">● Audit is a systematic approach to peer review of clinical or social care in order to identify possible improvements and to provide a mechanism for bringing them about● Audit raises questions that might be answered by further research● Audit is a test of whether things are being done as they should. It compares current practice with current standards● Where service users or other service users are involved, they are treated alike during Audit investigations● Where users are directly involved, there is no placebo concept● Audit does not consider a completely new treatment, but tests the adherence to a treatment that is considered to be best practice● Audit results are "local" to the test population/location/time● Audit requires the voluntary participation of specialities and departments. The data recorded and analysed relate only to that area● Audit investigations are published, usually at local level, to educate and publicise how to achieve best practice● Audit is a continuous and ongoing process which includes a follow-up investigation after a period of time

WHO IS AFFECTED?

1.13 Listed below are some of the individuals and organisations involved in health and social care research:

- service users, their relatives 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
- HSS care organisations
- voluntary and not-for-profit organisations
- the pharmaceutical and other industries
- the Department
- the R&D Office

CONCLUSION

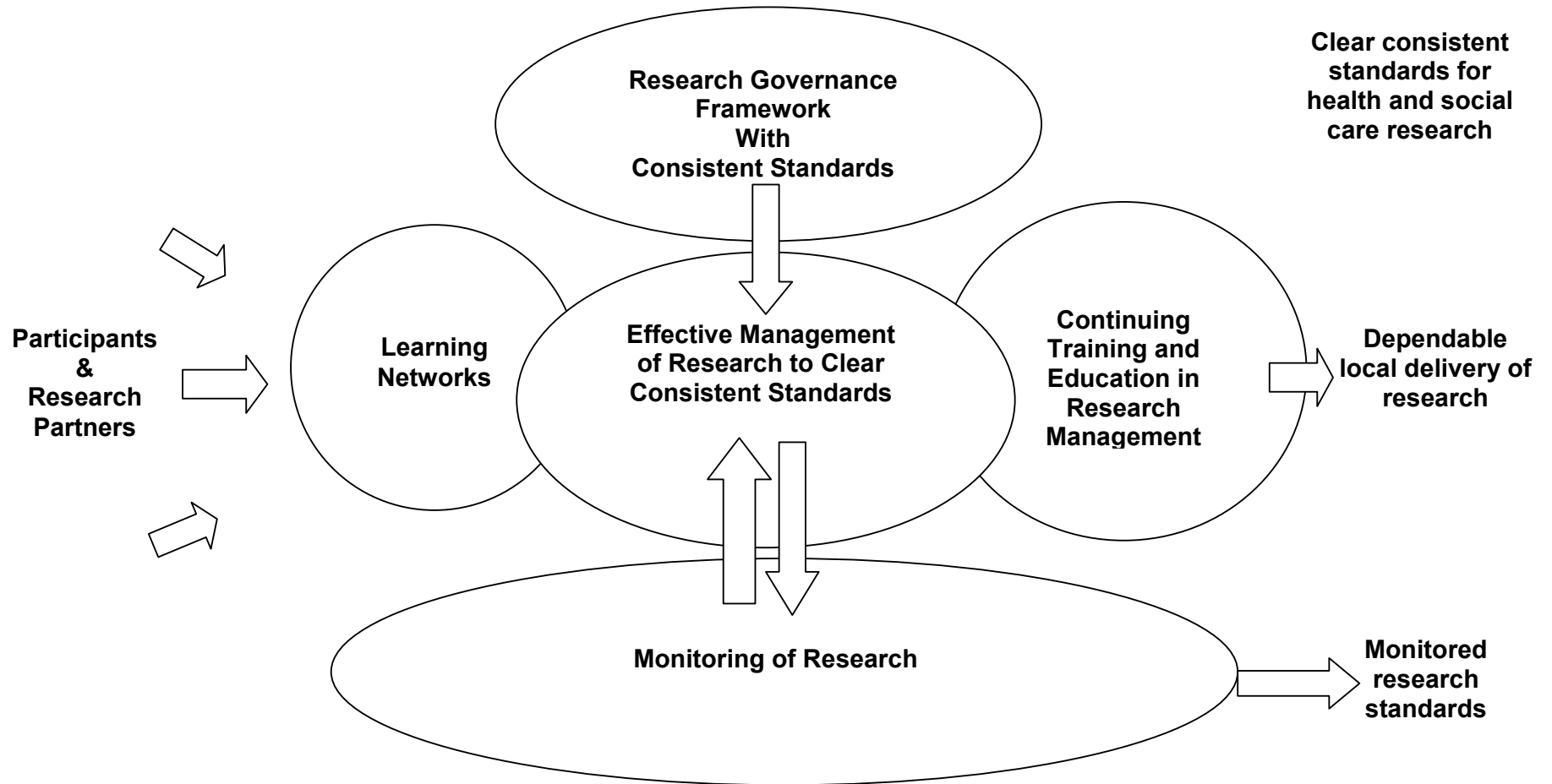
1.14 Achieving high quality in research depends on co-operation between all those involved. Figure 1 (on page 10) illustrates how the Department will continue to work with service users and professionals, the public and its research partners to develop and implement this research governance framework to assure quality in health and social care research.

1.15 Following the model in Figure 1 the remainder of this document is structured as follows:

- Section 2 sets out standards
- Section 3 details responsibilities
- Section 4 outlines delivery and monitoring systems

FIGURE 1 RESEARCH GOVERNANCE FRAMEWORK FOR HEALTH AND SOCIAL CARE

WHAT THE RESEARCH GOVERNANCE FRAMEWORK MEANS FOR PARTICIPANTS



Section 2 Standards

INTRODUCTION

- 2.1 Clinical and social care governance aims to improve the overall standards of clinical and social care in the HPSS and to reduce unacceptable variations in clinical and social care practice. Under the HPSS (Quality, Improvement and Regulation) (NI) Order 2003, there is a statutory duty of quality in place in the HPSS. This sets accountability at a local level for the delivery of services and for continuous improvement in quality.
- 2.2 The Department is developing a range of standards to support the HPSS in implementing the statutory duty of quality. These include:
- controls assurance standards which will assist HPSS organisations in managing their businesses, meeting their objectives and protecting against risk
 - care standards for an extended range of regulated services which will help ensure greater consistency in the quality of services provided across Northern Ireland
 - high-level Quality Standards for Health & Social Care that will integrate key elements of quality and safety
- 2.3 This activity is being led by the Department's Planning and Performance Management Directorate and comes within the remit of the Directorate's Standards and Guidelines Unit established to provide a single focus within the Department for the development and dissemination of standards and guidelines to the HPSS. The Unit has also established links with national standards and best practice bodies, and is developing mechanisms for the systematic handling of this guidance in the context of the HPSS.
- 2.4 The HPSS Regulation Quality and Improvement Authority (RQIA) has responsibility for monitoring and inspecting the availability and quality of health and social care services in Northern Ireland and for encouraging improvements. The Authority has responsibility for approving and granting registration in relation to a range of services such as nursing homes and residential care. The new standards will assist the new Authority in its work by providing a platform for assessing, and reporting on, the quality of care commissioned or provided by HPSS organisations and independent providers.
- 2.5 Health and social care research is not the province of a single discipline, profession or organisation and it is difficult for a single document to adequately capture the full range of legislation, standards and guidelines that need to be applied across this wide ranging body of work. They are presented within the framework document in five domains:

- Ethics
- Science
- Information
- Health, Safety and Employment
- Finance and Intellectual Property

ETHICS

- 2.6 The dignity, rights, safety and well-being of participants must be the primary consideration in any research study. Box D (page 19) describes a scenario to illustrate good practice in protecting research participants' rights within a study.
- 2.7 The Department requires that all health and social care research involving service users, care professionals or volunteers, or their organs, tissue or data, is reviewed independently to ensure it meets ethical standards².
- 2.8 Informed consent is at the heart of ethical research. All studies must have appropriate arrangements for obtaining consent and the ethics review process must pay particular attention to those arrangements. The Department issued guidance on Consent to Examination, Treatment or Care in 2003. This guidance outlines principles to be adhered to in obtaining informed consent, which would also apply to obtaining consent for research.
- 2.9 When research involves tissue or organs it must comply with the provisions of the Human Tissue Act 2004, which came into effect in 2006. 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.
- 2.10 The appropriate use and protection of service user data is also paramount. All those involved in 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 these systems. The Department has produced “The

² 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.

Protection and Use of Patient and Client Information – Guidance for the HPSS” available on the Department’s Website at http://www.dhsspsni.gov.uk/the_protection_and_use_of_patient_and_client_information.pdf. Particular attention should be paid to paragraph 4.21 of the guidance which emphasizes the need to advise service users about the planned use of their personal information.

- 2.11 Participants or their representatives should be involved wherever possible in the design, conduct, analysis and reporting of research. Active patient and public involvement is needed to encourage research which benefits and reflects the needs and views of patients and the public.
- 2.12 Research and those pursuing it should respect the diversity of human culture and conditions and take full account of equality issues such as religion, ethnicity, gender, disability, age and sexual orientation in its design, undertaking, and reporting. Researchers should take account of the multi-cultural nature of society. It is particularly important that the body of research evidence available to policy makers reflects the diversity of the population.
- 2.13 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 benefit³. Risks, pain or discomfort must always be kept to a minimum and explained clearly to the relevant ethics committee and to participants. Arrangements for compensation in the unlikely event of non-negligent harm must always be explained.
- 2.14 Some essential research into important illnesses and treatments can only be conducted with animals. When considering undertaking research which could involve the use of animals, alternatives such as cells, tissues, bacteria, plants and computer models must be considered and used wherever possible. Where animal use is unavoidable, there are strict statutory controls, enforced under the Animals (Scientific Procedures) Act 1986. Before a researcher can use animals, specific project and personal licences must be obtained from the Department; 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. In addition, there are three principles (the 3 Rs) that 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. The highest standards of animal husbandry and welfare under veterinary supervision must be maintained at all times and an ethical review

³ 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.

process must operate in accordance with the Departmental requirements.

SCIENCE

- 2.15 It is essential that existing sources of evidence, especially systematic reviews, are considered carefully prior to undertaking health and social care research. Research which duplicates other work unnecessarily or which is not of sufficient quality to contribute something useful to existing knowledge is in itself unethical.
- 2.16 All proposals 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 which is independent of the researcher. Arrangements for peer review must be commensurate with the scale of the research. For example, in the case of student research projects the university may provide an adequate level of review.
- 2.17 The Medicines for Human Use (Clinical Trials) Regulations 2004⁴ regulate trials of medicines on people. Authorisation by the Medicines and Healthcare products Regulatory Agency (MHRA) 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 trials⁵.
- 2.18 Special regulations govern the use of human embryos, the release of genetically modified organisms and food or food processes.
- 2.19 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 of good research practice by regulatory and other authorities.

⁴ The Medicines for Human Use (Clinical Trials) Regulations 2004 transposed Directive 2001/20/EC into UK law.

⁵ 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).

BOX C: PROTECTING RESEARCH PARTICIPANTS' RIGHTS

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

The scenario: A Professor of Social Work was awarded a grant by the R&D Office to study support services for adoptive families. The research involved the study of adopted children and their parents. The study included children aged between 8 and 14.

The study involved a survey of, and interviews with, a sample of adoptive parents. The research team sent the adoptive parents a letter and standard information sheet about the children's study. The information provided aimed to help them come to a decision about whether to support their child's participation in the research. It covered the project aims, interview arrangements, interview topics, and consent and confidentiality. It invited them to discuss over the phone any aspect of the study with the research team.

Enclosed with the parents' letter and information sheet was an information pack for them to pass on to their child. The letter noted that the child might be puzzled by its arrival, and suggested that it might be helpful for them to explain that they have already taken part in the project. Before handing the pack to their adopted child, the parents had some questions about the study that the mother put to the lead researcher over the phone. The researcher clarified that the mother was speaking for herself and the child's adoptive father.

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 daughter may be keen to take part, but I'm worried she might find it upsetting.

Researcher – I can't really say that 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 it might be particularly helpful for the interviewer to be aware of?

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, her teachers, or anyone else she knows. But 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 view of adoption. We particularly need to know if support services need to be improved for adopted children and their families. The study has been commissioned by the Department and the findings will be fed directly into the Department's review of adoption. A panel of experts have checked the scientific design and it has undergone an ethical review.

BOX C: CONTINUED

Parent – If she says 'yes' can she pull out later?

Researcher – Yes. She can change her mind whenever she wants. We have 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 will be a summary of our findings especially written for all 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.

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 adoption. 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 – Can I change my mind?

Researcher – Yes, of course. You can change it at any time.

Child – What if I'm not sure?

Researcher – Take your time. We don't need to know straightaway. Talk to someone else about it if that helps, but it would be helpful if you could let me know in about three weeks time. If I have not heard from you by 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.

This researcher is trying to do the right things in the right way. The principles of the research governance framework are reflected in her practice.

2.4 INFORMATION

- 2.20 Health and social care research is conducted for the benefit of service users, care professionals, and the public in general. There should be free access to information both on the research being conducted and on the findings of the research, once these have been subjected to appropriate scientific review. This information must be presented in a format understandable to the public. Reports need to be comprehensible and take language and other needs into account.
- 2.21 Some advances in health and social care need to be developed commercially if they are to be made widely available. Drugs, medical devices and aids for disabled people are examples. Successful commercial development often depends upon the effective protection of intellectual property or commercial confidentiality at critical points in the innovation process⁶. The timing of the publication of research findings needs to take account of this.
- 2.22 All those conducting health and social care research should aim to ensure that their findings are available to others through appropriate dissemination. This will usually entail publishing their work. Research findings must be subjected to critical review through the accepted scientific and professional channels. Where studies involve direct contact with service users (including the relatives of deceased users who have consented to the use of organs or tissue in the research), or the public, researchers should provide accessible accounts of the research and, when completed, of its findings to those involved, including to the study participants⁷.

HEALTH, SAFETY AND EMPLOYMENT

- 2.23 Health and social care 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.

FINANCE AND INTELLECTUAL PROPERTY

- 2.24 Financial probity and compliance with the law and with the rules laid down by Department of Finance and Personnel and HM Treasury for the use of public funds are as important in research as in any other area.
- 2.25 Organisations employing researchers must be in a position to compensate anyone harmed as a result of their negligence. Any

⁶ Researchers are advised to consult the HPSS Innovations Advisor at the Clinical Research Support Centre.

⁷ 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.

organisation offering participants compensation in the event of non-negligent harm must be in a position to do so.

2.26 Careful consideration must be given to the appropriate exploitation of intellectual property rights.

QUALITY RESEARCH CULTURE

2.27 Some of the principles and requirements applying to health and social care 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 correctly. A quality research culture is thus essential for proper governance of health and social care research.

2.28 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

2.29 Box D (page 19 and 20) illustrates how research is managed in a HSS body with a quality research culture.

BOX D: STANDARDS IN A QUALITY ORGANISATION UNDERTAKING RESEARCH

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 Departmental priorities and needs, the organisation's business, to clinical and social care governance (in HPSS organisations) and the delivery of best value.
- The organisation's research strategy values diversity in its service users and its staff and promotes their active participation in the development, undertaking and use of research.
- The organisation promotes a culture that is sensitive to the needs of more vulnerable groups that are involved in research.

Ethics

- All research which involves patients, service users or care professionals and other staff or their organs, tissue or data is referred to 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 animal use is unavoidable the highest standards of animal husbandry are maintained under veterinary supervision.

Science

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

Health, Safety & Employment

- The organisation's human resource strategy included 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 office, laboratory and field work. It follows Good Laboratory Practice, Good Manufacturing Practice in manufacturing products for clinical trials and Good Clinical Practice in conducting clinical trials.

BOX D: (Continued)

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 that patients, service users, carers, health and social 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 to research ethics committees.
- 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.

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 Department of Finance and Personnel. It complies with all audit required by external funders or sponsors and has systems in place to deter, detect and deal with fraud.
- The organisation has in place indemnity arrangements as part of their system of safeguards.
- 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.

Section 3 Responsibilities and Accountability

GENERAL

- 3.1 All those involved in research with human participants, their organs, tissues or data must be aware of and implement the law and the basic principles 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 or social care research study. It is essential that clear agreements describing allocation of responsibilities and rights for a study are developed, documented and enacted.
- 3.4 While many agreements relate to individual studies, organisations that collaborate on a range of research work may find it helpful to develop and document framework agreements to facilitate the agreement of responsibilities for specific studies. Examples of collaborations where framework agreements are necessary include:
- HSS bodies (eg Trusts, special agencies, HSS Boards and the new HSS Authority) who work together regularly on research, whether or not in a formal network
 - universities and HSS bodies that work together regularly on research
- 3.5 It is particularly important that clear and documented agreements are in place for complex studies where there may be:
- work on more than one site
 - researchers employed by more than one organisation
 - users and professionals from more than one organisation; and/or more than one funder
- 3.6 The NHS/HPSS R&D Partnership with the Pharmaceutical Industry launched in 2003 sets out principles for industry involvement in commercial contract research and in collaborative studies. A model Clinical Trial Contract (mCTA), revised in 2006, is intended for use in those clinical trials, sponsored by pharmaceutical and biotech

companies, which involve HPSS service users. The mCTA is designed to speed up the initiation of trials whilst providing the assurance that appropriate arrangements are in place to protect service users and the organisations responsible for their care. A Northern Ireland specific version of the mCTA is available and is endorsed for routine use without amendment by the Department, the Association of the British Pharmaceutical Industry, the Bio Industries Association, the Council of Heads of Medical Schools, the UK Clinical Research Collaboration and the NHS R&D Forum. For contract clinical trials in secondary care, clinical trial agreements will be between the commercial sponsor and each HSS body accountable for the care of HPSS 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 HSS body depending on the circumstances.

SPECIFIC RESPONSIBILITIES

- 3.7 Box E (page 23-24) describes the people and organisations that may be involved in a health and social care research study. The key responsibilities of the people and organisations accountable for the proper conduct of a study are summarised in Box F (page 28-29).
- 3.8 The remainder of this section sets out these responsibilities in more detail. Box G (page 38 - 40) illustrates these responsibilities by way of a scenario.

**BOX E:
MAIN PEOPLE AND ORGANISATIONS
INVOLVED IN A HEALTH OR SOCIAL CARE
RESEARCH STUDY**

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.)

Chief Investigator⁸

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. For clinical trials involving medicines, the Chief Investigator must be an authorised health professional.

Principal Investigator⁸

Person responsible for the conduct of the clinical trial at an individual trial site. If a trial is conducted by a team of individuals at a trial site, the investigator leading the team is called the Principal Investigator. For clinical trials involving medicines, the Principal Investigator must be an authorised health professional.

Researchers/Investigators

Members of the research team other than the Chief Investigator or the Principal Investigator. For clinical trials involving medicines, an investigator must be an authorised health professional.

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.)

⁸ The terms Chief Investigator (CI), Principal Investigator and Investigator (PI) are used in different contexts with a variety of regulatory/legislative origins. All research studies must be led by a CI irrespective of the number of sites/centres involved. There can only be one CI for any given study. The role of CI cannot be split between more than one person. The term PI only becomes relevant where a research study involves more than one site/centre. In those sites/centres other than the co-ordinating site/centre the lead researcher is referred to as the PI. The PI may be the sole investigator at a site/centre or lead a team of investigators.

BOX E: (continued)

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.

Organisation providing care

Organisation responsible for providing health and/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.

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.

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 Committees Authority.

RESPONSIBILITIES OF PARTICIPANTS

- 3.9 Improvements in effective and responsive services depend upon research. Through this framework and related provisions, the Department and its research partners will strive to ensure that research conducted in health and social care offers the likelihood of real benefits either to those who participate, or those who use services subsequently, or both. All those using the HPSS should give serious consideration to invitations to become involved in the development or undertaking of research studies.
- 3.10 Researchers must develop 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.

RESPONSIBILITIES OF RESEARCHERS

- 3.11 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 study protocol
 - 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
 - reporting any failures in these respects, or suspected misconduct, through the appropriate systems

RESPONSIBILITIES OF THE CHIEF INVESTIGATOR

- 3.12 A senior individual must be designated as the Chief Investigator for any research undertaken in or through the HPSS, which involves participants or their organs, tissue or data. There can be only one Chief Investigator and this role cannot be split between one or more individuals. The Chief Investigator 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, and co-ordinating the investigators who take the lead at each site.

- 3.13 Chief Investigators must have suitable experience and expertise in the design and conduct of research⁹ 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
- 3.14 For health and social care research, the Chief Investigator is responsible for ensuring the following:
- the research team gives priority at all times to the dignity, rights, safety and wellbeing of participants
 - the research study complies with all legal and ethical requirements
 - the research is carried out to the standards in this research governance framework
 - trials involving human participants must be 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 proposed, 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 an HSS Trust, the appropriate director or 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

⁹ 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.

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 necessary¹⁰, the research follows the protocol agreed by the relevant research ethics committee and by the sponsor¹¹
- substantive changes to the protocol or proposal are submitted for ethical review and for the sponsor's agreement¹². These amendments are implemented only when approved
- procedures are kept in place to ensure collection of high quality, accurate data and the integrity and confidentiality of data during processing and storage¹³
- there are appropriate arrangements to archive the data when the research has finished, and to make it accessible
- 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

¹⁰ Investigators in clinical trials involving medicines have to report serious adverse events immediately.

¹¹ 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).

¹² Also, for clinical trials involving medicines, to the licensing authority.

¹³ 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.

**BOX F:
SUMMARY OF KEY RESPONSIBILITIES OF PEOPLE AND ORGANISATIONS
ACCOUNTABLE FOR THE PROPER CONDUCT OF A 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 sections, 3.11 - 3.14

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(s) and other key researchers involved.
- Requiring that a sponsor takes on responsibility before the research begins.

See sections, 3.15 - 3.19

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.
- 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 section, 3.20 - 3.25

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 section, 3.26 - 3.29

BOX F: (continued)

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 section, 3.30 - 3.33

RESPONSIBILITIES OF RESEARCH FUNDERS

- 3.15 Organisations that fund research have a responsibility for ensuring that the work is a proper use of the funds they control and provides value for money.
- 3.16 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 money¹⁴.
- 3.17 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
 - 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.

- 3.18 Funders are expected to provide assistance to any enquiry, audit or investigation related to the funded work.
- 3.19 Funders are expected to make their funding conditional on identifying a sponsor. Organisations wishing to fund research requiring the collaboration of the HPSS 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 are ready in principle to sponsor studies within programmes of research funded by the Department or the HPSS.

¹⁴ 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 RESEARCH SPONSOR

3.20 The sponsor is the individual, or organisation (or group of individuals or organisations) that takes responsibility for confirming there are proper arrangements to initiate, manage and monitor, and finance a study¹⁵. For any research that takes place in the context of the HPSS 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 Kingdom¹⁶, it must have a legal representative in the United Kingdom. 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.

3.21 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
- to allocate 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
- approve any modifications to the design, obtain any regulatory authority required, implement them, and make them known

3.22 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

¹⁵ 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.

¹⁶ The Regulations require a sponsor to be established, or have a legal representative, in the European Community. Neither of them needs to be established in the United Kingdom.

will operate the management and monitoring systems.

3.23 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.

3.24 Where research has no external sponsor, care organisations may, if they wish the unsponsored research to proceed, accept the responsibility of the sponsor. For example, an HSS Trust may be willing, and able, to act as the sponsor for research which does not have an external sponsor (sometimes called "own account" research). Alternatively an HSS Trust may decline the opportunity for that research to proceed within its care organisation.

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

- the research study respects the dignity, rights, safety and wellbeing of participants and the relationship with care professionals
- an appropriate process of independent expert review has demonstrated the research study to be worthwhile, of high scientific quality and good value for money
- an appropriate research ethics committee or independent ethics reviewer 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 developments¹⁷ during

¹⁷ For clinical trials involving medicines, these include serious adverse events, serious adverse reactions, and suspected unexpected serious adverse ad defined in the Medicines for Human Use (Clinical Trials) Regulations 2004.

the study, whether in relation to the safety of individuals or to scientific direction¹⁸

- agreement has been reached about compensation in the event of harm to research participants¹⁹; 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

The sponsor is expected to assist any enquiry, audit or investigation related to the research.

RESPONSIBILITIES OF ORGANISATIONS EMPLOYING RESEARCHERS

3.26 Employers of staff undertaking health and social care research have responsibility for developing and promoting a 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 complaints. These responsibilities apply to both private and public sector employers.

3.27 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 reporting²⁰.

3.28 Employers should ensure that agreements are in place 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.

¹⁸ 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.

¹⁹ 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.

²⁰ 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.

- 3.29 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 the Chief Investigator and/or 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 in place 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 their staff and, if they have agreed to do so, for non-negligent harm arising from the research
 - having in place systems to detect and address fraud, and other scientific or professional misconduct by their staff
 - having in place systems to process, address and learn lessons from any complaints brought against their employees
 - permitting and assisting in any investigation arising from complaints received in respect of actions taken by their employees

RESPONSIBILITIES OF ORGANISATIONS PROVIDING CARE

- 3.30 All organisations providing health and social care must be aware of all research being undertaken in their organisation, and any research involving participants, organs, tissue or data obtained through the organisation. They should ensure that their service users 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.
- 3.31 Organisations providing care are also responsible for ensuring that any research involving their service users and carers or staff meet the standards set out in this framework, in particular that it has an identified research sponsor willing and able to discharge its responsibilities, and that clear and documented agreements are in place about the allocation of responsibilities between all parties involved. Accountability for this lies with the Chief Executive but he or she may delegate responsibility for ensuring compliance to an appropriately qualified and senior member of staff, eg, the organisation's director of research and development. The care provider remains responsible for the quality of all aspects of the care of their users, whether or not they are involved in research and by whoever that research may be conducted or funded.

- 3.32 Chief Executives of HSS bodies are accountable for quality under the statutory duty of quality as described in the clinical and social care governance guidance. Researchers not employed by the HSS body who interact with individuals in a way which has direct bearing on the quality of their care should hold an honorary contract prior to commencing their research.
- 3.33 A summary of the main 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
 - be aware and maintain a record of all research work being undertaken through or within the organisation, including research undertaken by students as part of their training
 - ensure service users and carers are provided with information on research that may affect their care
 - be aware of any current legislation relating to research work and ensure that this is implemented effectively within the organisation
 - ensure that all research has been approved by an appropriate research ethics committee
 - ensure that all research has an identified sponsor who understands, accepts and is able to discharge their duties as set out in this framework
 - ensure a person authorised to do so has given written permission on behalf of the organisation providing care
 - ensure that written agreements are in place regarding responsibilities for all research involving an external partner, funder and/or sponsor, including agreement with a university or other employer in relation to student supervision
 - ensure that the necessary links with clinical and social care governance are made
 - ensure that non-HPSS employed researchers hold honorary contracts where appropriate and that there is clear accountability and understanding of who is responsible for what
 - put in place and maintain the necessary systems to identify and learn from errors and failures
 - put in place and maintain the necessary systems to process, address and learn lessons from complaints arising from any research work being undertaken through or within the organisation
 - ensure that significant lessons learnt from 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 adverse events reporting in social care
 - permit and assist with any monitoring, auditing or inspection required by relevant authorities

RESPONSIBILITIES OF CARE PROFESSIONALS

- 3.34 Health and social care staff retain responsibility for the care of their service users, when they are participating in research.
- 3.35 Before agreeing to their service users being approached, they must satisfy themselves that the research has been the subject of approval by appropriate scrutinising authorities within their organisation or agency, and that any research that relates directly to the care they provide complies with this framework.

RESPONSIBILITIES RELATING TO RESEARCH ETHICS COMMITTEES

- 3.36 No research study within the HPSS involving individuals, their organs, tissue or data may begin until it has a favourable opinion from an HPSS Research Ethics Committee (HPSS REC). These committees are supported by the Office for Research Ethics Committees for Northern Ireland (ORECNI). The HPSS RECs together with ORECNI constitute the Research Ethics Service for Northern Ireland and form part of the UK NHS Research Ethics Service.
- 3.37 The United Kingdom Ethics Committees Authority (UKECA) is responsible for recognising ethics committees to review clinical trials under the Medicines for Human Use (Clinical Trials) Regulations 2004. The Human Tissue Act 2004 also requires ethical review by an appropriate body; normally, a research ethics committee.
- 3.38 The Central Services Agency (CSA) is responsible for establishing and supporting HPSS RECs. These committees are established to review both health and social care research within the HPSS. Those outside the HPSS may also seek the advice of these committees.
- 3.39 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. While they operate within a framework of standards and HPSS management, neither the DHSSPS nor any HSS body is entitled to interfere with the HPSS RECs' decisions. The CSA as the HPSS RECs' appointing authority must maintain systems to appoint members, to convene them, to seek recognition by UKECA, and to support them and monitor their performance. HPSS RECs are established to review both health and social care research in the HPSS.
- 3.40 Ethics committees provide an independent opinion. The decision whether or not to give permission for research to proceed in a care organisation rests with that organisation. 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.

- 3.41 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 organisations²¹ 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.
- 3.42 HPSS RECs should adhere to the provisions of the Governance Arrangements for Research Ethics Committees (GaFREC). Responsibility for assuring the scientific quality of a research study normally rests with the funder. It is not the task of RECs to undertake additional scientific review, but to satisfy themselves that the review undertaken is adequate given the nature of the proposal.
- 3.43 HPSS RECs require researchers working in the HPSS 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 progress²².

²¹ And the sponsor, for clinical trials involving medicines.

²² 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.

BOX G: SPECIFIC RESPONSIBILITIES OF KEY PEOPLE INVOLVED IN RESEARCH

WHO IS RESPONSIBLE FOR WHAT? – SOME QUESTIONS AND ANSWERS

The Scenario: *A university Senior Lecturer in General Practice is awarded a grant by the Medical Research Council (MRC) to conduct a trial on an existing drug but outside of its existing licence. The grant is paid to the university. The MRC was closely involved in the development of the trial design, and the study is based in the MRC's General Practice Research Framework. The manufacturer of the drug has agreed to provide it free. The research is taking place in general practice. It is agreed that the university should take on the responsibilities of sponsor.*

PATIENT

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

A: **Your GP has agreed to join this study 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, as funder, assessed the clinical importance of the questions addressed by the study. It also assessed the design and oversight arrangements. One of the HPSS Research Ethics Committees checked it is ethical. The MHRA authorised the use of the drug in this clinical trial.**

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 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 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.**

GP

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

A: **The university is sponsoring the study. The protocol names the sponsor's 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 in which 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 a number of my patients are having trouble understanding what they are being asked to take part in and why. It's taking up an enormous amount of time. What should I do?*

A: **You should 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.**

BOX G: (Continued)

GP continued

Q: *Who is responsible for ensuring that the study is conducted according to the protocol and that the 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.**

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: **You have a primary responsibility for 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 that you notify the Chief Investigator of any concerns you have 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 Central Office for Research Ethics Committees (CORECs) website. You need a positive ethics committee opinion as well as a Clinical Trial Authorisation before you can start the trial. (To come within HPSS indemnity, you also need permission from each HSS Trust before you seek to recruit anyone covered by that organisation's duty of care).**

Q: *To whom must I report an adverse event?*

A: **For this trial, the sponsor has 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.**

BOX G: (Continued)

Q: *I am concerned that the staff in the university labs are not following appropriate 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 that 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 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 this to the sponsor. As funder, the MRC should also be informed. They may decide that the revised protocol should go through a further process of scientific review. The amended protocol must also be submitted to both the MHRA and 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 think I have generated some important intellectual property. What should I do?*

A: **Your employer as sponsor 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 cooperate. 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.**

Section 4 Achieving Governance

DELIVERY SYSTEMS

- 4.1 Organisations undertaking, sponsoring, funding or hosting health and social care research must have systems in place to ensure that they and their staff understand and follow the standards and good practice set out in this framework. In Northern Ireland the R&D Office will, on behalf of the Department, lead in taking forward the research governance agenda. The R&D Office working with partner organisations will:
- provide a regional perspective on the development and maintenance of proper research governance
 - lead on the development of appropriate research governance policies for the HPSS, providing a comprehensive underpinning framework and offering a comprehensive set of research governance policies for adoption by individual HSS bodies
 - unify, co-ordinate and streamline research governance procedures in the areas of regulation, approvals, management and reporting in a manner that minimises bureaucracy and maximises effectiveness
 - develop and maintain common systems which support a combination of centralised and decentralised functions designed to address the needs of all those involved in HPSS R&D
 - seek to ensure that research governance is delivered in a manner that: facilitates R&D integration with patient care; removes unnecessary barriers to research in the HPSS; helps service users participate in and benefit from HPSS R&D; and protects the rights and safety of all those involved in HPSS R&D
- 4.2 Research funders should have systems in place, or have access to systems to undertake expert independent review – appropriate to the scale and complexity of research proposals – to ensure the scientific and ethical standing of any proposed research study, its strategic relevance and value for money.
- 4.3 Research sponsors must ensure that systems are in place – managed either by themselves or by one of the organisations involved in the research, such as the host university, a funding body, or care provider – to ensure that all research they sponsor is conducted according to the agreed protocol, to monitor its general progress and to discuss and agree modifications to the protocol if the need arises.
- 4.4 All health and social care providers must have systems in place to ensure that they are aware of, and have given permission for, all research being conducted in or through their organisation, whether or not it is externally funded. Care providers should only give permission for research which has a sponsor. Care providers may only themselves

take on the role of sponsor if they have systems in place to discharge those responsibilities. It is acceptable for an individual employee to be a sponsor, but only with the written permission of that person's employer²³. Whoever acts as sponsor, care providers must satisfy themselves that systems are in place, either in their own organisation or elsewhere, to ensure that all research conducted in or through their organisation conforms to appropriate scientific and ethical standards, and offers value for public money.

- 4.5 Nothing in this research governance framework is intended to transfer the legal duties of health and social care organisations to sponsors or to others. Irrespective of whoever takes on sponsorship, if a study affects an HSS body's duty of care, it remains that organisation's responsibility to satisfy itself that there are systems in place to ensure a research study is conducted to appropriate scientific and ethical standards.
- 4.6 HPSS RECs and expert 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. In 2005, the National Patient Safety Agency became responsible for the Central Office for Research Ethics Committees (COREC), providing advice, assistance and national systems to support the work of research ethics committees. In Northern Ireland, HPSS RECs are supported by ORECNI which is closely linked to COREC.
- 4.7 Delivery systems should be designed to detect failures to adhere to requirements, regardless of whether such failures arise by intent or oversight. Such systems should involve routine and random monitoring and audit as appropriate. Additionally, delivery systems should require, facilitate and support reporting of critical incidents, near misses, systems failures and misconduct either by self-reporting or whistle-blowing.
- 4.8 Research governance depends critically on research workers and research managers understanding their responsibilities and having the skills needed to discharge them. The Department through the R&D Office will work with other research funders; the universities and HSS bodies involved in research to promote the awareness of research governance.

²³ 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.

MONITORING, INSPECTION AND FAILURES

- 4.9 Organisations and individuals must be able to demonstrate adherence to this framework to reassure service users and care professionals of the quality of their services and to assure their reputation in high quality research and care.
- 4.10 There are already incentives to adhere to many of the principles and standards set out in the framework. These include the law, the duties of care and the duty of quality in the HPSS and the high professional and ethical standards upheld by the majority of care professionals and researchers. Mechanisms, which monitor the quality of clinical and social care such as audit, risk management and staff appraisal can assist in the monitoring of research governance at a local level. Nevertheless, a coherent system is needed to monitor performance against this research governance framework, to identify best practice and shortfalls, to enhance public confidence and help to prevent adverse events. Where minimum acceptable standards are not met, sanctions are needed.
- 4.11 Arrangements will be established to work with and through structures that already exist or are being developed in HSS bodies, 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
 - HSS bodies participating in research
 - universities and other organisations employing researchers
 - other organisations on which this framework depends
- 4.12 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/HPSS. 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.
- 4.13 The Department will introduce research governance as one of the core standards all organisations should achieve in delivering HPSS care. HSS 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.

- 4.14 There is public and professional concern about research misconduct and fraud, though its extent is unknown. Monitoring of research governance will check that appropriate systems are in place to detect and investigate possible fraud and to take appropriate action if fraud is found. In addition, HSS bodies should themselves ensure that universities and any other organisations with whom they develop partnerships have appropriate systems for detecting, investigating and addressing fraud by their employees.
- 4.15 Failures on the part of staff in the Department or the HPSS to comply with the requirements of this framework, or to meet their responsibilities relating to this framework, will be addressed through normal management channels and disciplinary procedures. The Department will look to those with responsibilities within HSS bodies or in other organisations to address any shortcomings which exist. Departmental and HPSS R&D funds will only be allocated to those competent to manage the work they support. It is the responsibility of other organisations to have appropriate systems in place to address failures by their staff. Monitoring arrangements will verify that these are in place. Where such a failure occurs, University employees with HPSS honorary contracts may have these withdrawn, subject to a joint HPSS/university investigation.
- 4.16 In the case of misconduct, some professional groups will be subject to disciplinary action by their professional bodies. Doctors are responsible to the General Medical Council for their professional conduct as researchers as well as clinicians. Similarly, dentists are responsible to the General Dental Council, nurses, health visitors and midwives are responsible to the Nursing and Midwifery Council and Allied Health Professionals are responsible to the Health Professions Council. Misconduct by social care professionals will be the responsibility of the Northern Ireland Social Care Council.
- 4.17 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.

Linked Documents

This document builds on a range of earlier published work and draws extensively on the following documents as outlined in Box H:

BOX H: PUBLICATIONS	
Best Practice – Best Care	April 2001
Confidence in the Future	October 2000
Research Governance Framework for Health and Social Care (2 nd edition)	DH 2005
Research Governance Framework for Health and Community Care	Scottish Executive 2006
Research Governance Framework for Health and Social Care in Wales	National Assembly for Wales 2001
MRC Guidelines for Good Clinical Practice in Clinical Trials http://www.mrc.ac.uk	MRC 1998
OST Guidelines on Use of Scientific Advice in Policy Making http://www.dti.gov.uk/ost/ostbusiness/index_policy_making_old.htm	2000

Produced by:
Department of Health, Social Services & Public Safety
Castle Buildings
Belfast BT4 3SJ

028 90 524310
www.dhsspsni.gov.uk