

# RESEARCH GOVERNANCE

## STANDARD

**Health and Social Care organisations which either lead or participate in research activities adhere to, and apply consistently, the principles and requirements of the Research Governance Framework.**

## OVERVIEW

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, research can involve an element of risk, both in terms of return on investment and sometimes for the safety and well-being of the research participants. Proper governance of research is therefore essential to ensure that the public can have confidence in, and benefit from, quality research in health and social care. The public has a right to expect high scientific, ethical, and financial standards, transparent decision-making processes, clear allocation of responsibilities and robust monitoring arrangements.

The Department of Health, Social Services and Public Safety *Research Governance Framework for Health and Social Care* published in December 2006 gives guidance on good practice in the collaboration between researchers, health and social care teams and their employers and funders. This replaces the November 2001 draft framework taking account of: the EU Clinical Trials Directive 2001/20/EC transposed in to UK law as The Medicines for Human Use (Clinical Trials) Regulations 2004; and the Human Tissue Act 2004.

It is now available at:

[http://www.dhsspsni.gov.uk/research\\_governance\\_framework.pdf](http://www.dhsspsni.gov.uk/research_governance_framework.pdf)

and

[http://www.centraleservicesagency.n-i.nhs.uk/files/rdo\\_whats\\_new/file/RGF\\_061106.pdf](http://www.centraleservicesagency.n-i.nhs.uk/files/rdo_whats_new/file/RGF_061106.pdf)

The Research Governance Framework covers all research activities undertaken in areas for which the Minister of Health has responsibility. That is research concerned with the protection and promotion of public health, research undertaken by or within the Department of Health Social Services and Public Safety, its non-Departmental Public Bodies and research undertaken by or within health and social care agencies. This includes clinical and non-clinical research, research undertaken by HSC staff using HSC resources, and any research undertaken by industry, the charities, the research councils and universities within the health and social care systems that might have an impact on the quality of those services.

Research can be defined as the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods. The

document sets out the responsibilities and standards that apply to work managed within the formal research context. Other documents on clinical governance and on quality in the HSC and social care set out standards and systems for assuring the quality of innovative work in non-research contexts.

The RESEARCH GOVERNANCE FRAMEWORK is intended to sustain a quality research culture that promotes excellence, with visible research leadership and expert management to help researchers, clinicians and managers apply standards correctly. 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
- Written procedures and staff training

Whilst the Controls Assurance standards currently only apply to the Health and Social Services (HSS) Boards, Trusts and special agencies, other healthcare providers such as Independent Contractors (GP Practices, Dentists, Pharmacists, optometrists etc) are encouraged to adopt the principles embodied within each of the criteria.

The suggested examples of source and verification provided within the standard are merely illustrative and auditable examples, which may be used to verify compliance with a particular criterion. Trusts and other HSS bodies may wish to consider and use other relevant examples, which may vary depending on the nature of a particular organisation. These alternative means of evidence may be just as valid as the illustrative examples provided in this standard.

## KEY REFERENCES

The majority of documents appearing on this page are downloadable in PDF (Portable Document Format). Viewing these requires **Adobe Acrobat Reader** on your computer. If you do not have this free software, you are advised to contact your system administrator to arrange for a copy to be installed on your computer. Alternatively Adobe Acrobat can be downloaded directly from Adobe's website <http://www.adobe.com/acrobat>

The links below were all accurate at the time of publication.

DHSSPS & R&D Office (2006) Research Governance Framework For Health and Social Care: [http://www.dhsspsni.gov.uk/research\\_governance\\_framework.pdf](http://www.dhsspsni.gov.uk/research_governance_framework.pdf)

Department of Health (2006) Research Governance Framework for Health and Social Care 2<sup>nd</sup> Edition:  
[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4108962](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108962)

EU Clinical Trials Directive 2001/20/EC transposed in to UK Law as The Medicines for Human Use (Clinical Trials) Regulations (2004);  
<http://www.opsi.gov.uk/si/si2004/20041031.htm>

Human Tissue Act (2004); <http://www.opsi.gov.uk/acts/acts2004/20040030.htm>

Medical Research Council *Guidelines for Good Clinical Practice in Clinical Trials*  
<http://www.mrc.ac.uk/PolicyGuidance/EthicsAndGovernance/index.htm>

In line with the *Data Protection Act 1998: The Protection and Use of patient and Client Information*  
[http://www.dhsspsni.gov.uk/the\\_protection\\_and\\_use\\_of\\_patient\\_and\\_client\\_information\\_.pdf](http://www.dhsspsni.gov.uk/the_protection_and_use_of_patient_and_client_information_.pdf)

Great Britain (1998) *The Data Protection Act 1998* The Stationery Office, London.  
<http://www.hmsa.gov.uk/acts/acts1998/19980029.htm>

Health and Personal Social Services Act (Northern Ireland) 2001  
<http://www.opsi.gov.uk/legislation/northernireland/acts/acts2001/20010003.htm>

HPSS Executive (1999) For The Record - Managing records in HSC Trusts and Health Authorities HSC 1999/53 1999  
[http://www.info.doh.gov.uk/doh/coin4.nsf/12d101b4f7b73d020025693c005488a9/ecd5f68ba22dd17b002567390036ef68/\\$FILE/Hsc053.pdf](http://www.info.doh.gov.uk/doh/coin4.nsf/12d101b4f7b73d020025693c005488a9/ecd5f68ba22dd17b002567390036ef68/$FILE/Hsc053.pdf)

Office of Science and Technology (2000) The use of scientific advice in policy making: Implementation of the guidelines  
[http://www.ost.gov.uk/policy/advice/implement\\_98/](http://www.ost.gov.uk/policy/advice/implement_98/)

Department for Education and Skills (2001) *A Review of Appraisal, Disciplinary and Reporting Arrangements for Senior HSC and University Staff with Academic and Clinical Duties*  
[www.dfes.gov.uk/follettreview](http://www.dfes.gov.uk/follettreview)

HSS (PPM) 3/2002 Corporate Governance: Statement on Internal Control

HSS (PPM) 6/2002 AS/NZS 4360: 1999 – Risk Management

HSS (PPM) 8/2002 Risk Management in the Health and Personal Social Services

HSS (PPM) 10/2002 Governance in the HPSS – Clinical and Social Care  
Governance: Guidelines for Implementation

HSS (PPM) 13/2002 Governance in the HPSS: Risk Management

HSS (PPM) 5/2003 Governance in the HPSS: Risk Management and Controls  
Assurance

HSS (PPM) 6/2004 Reporting and Follow-up on Serious Adverse Incidents: Interim  
Guidance

HSS (PPM) 8/2004 Governance in the HPSS: Controls Assurance Standards –  
Update

HSS (PPM) 4/2005 AS/NZS 4360: 2004 – Risk Management

## INDEX OF RESEARCH GOVERNANCE CRITERIA

### **Criterion 1**

Board level responsibility for research governance is clearly defined and there are clear lines of accountability throughout the organisation, leading to the Board

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There is a designated person with responsibility for the management of all research undertaken within the organisation

### **Criterion 3**

The organisation ensures financial probity in all matters concerning research governance

### **Criterion 4**

The organisation has a written agreement with research partners documenting the allocation of research responsibilities

### **Criterion 5**

The organisation has arrangements in place to issue HSC honorary contracts to non-HSC researchers

### **Criterion 6**

All research undertaken within the organisation complies with statutory legislation and guidance

### **Criterion 7**

There is a system in place to record all adverse events arising from any research undertaken by the organisation and staff are made aware of and, where necessary, trained in adverse incident reporting requirements

### **Criterion 8**

All research undertaken within the organisation has a confirmed sponsor

### **Criterion 9**

The organisation has a system in place to detect and deal with research misconduct and fraud

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The organisation has systems in place to promote patient and public involvement in all stages of research activity.

### **Criterion 11**

There are systems in place to inform service users and members of the public about research undertaken within the organisation

### **Criterion 12**

All research conducted by an HSC organisation is appropriately disseminated.

### **Criterion 13**

The organisation has systems in place for the appropriate management of intellectual property

**Criterion 14**

The organisation ensures that all relevant staff are aware of their roles and responsibilities with regard to the research governance framework

**Criterion 15**

Key indicators capable of showing improvements in research governance and/or providing early warning of risk are used at all levels of the organisation, including the Board, and the efficacy and usefulness of the indicators is reviewed regularly

**Criterion 16**

The system in place for managing research governance, including risk management arrangements, is monitored and reviewed by management and the Board in order to make improvements to the system

**Criterion 17**

The Board should seek independent assurance that an appropriate and effective system of research governance is in place and that the necessary level of controls and monitoring are being implemented

## CRITERION 1

**Board level responsibility for research governance is clearly defined and there are clear lines of accountability throughout the organisation, leading to the Board.**

### INFORMATION

#### Source

- Department of Health Social Services and Public Safety (2006) Research Governance Framework for Health and Social Care
- HSS (PPM) 3/2002 Corporate Governance: Statement on Internal Control
- HSS (PPM) 10/2002 Governance in the HPSS – Clinical and Social Care Governance: Guidelines for Implementation.
- Standards Australia (1999) Risk Management AS/NZS 4360:2004. Standards Association of Australia. Strathfield NSW.

#### Guidance

Research is an important activity within HPSSHSC organisations and represents a potential area of significant risk. Clear leadership at Board level is therefore essential if research is to be managed strategically and is to apply the standards set out in the Research Governance Framework.

Ultimately, the Chief Executive is responsible for ensuring that there are effective systems in place to discharge these responsibilities. These systems should include the appointment of a nominated Executive Director with defined responsibility for research governance and with adequate resources to ensure compliance with the Research Governance Framework, which are commensurate with the risks arising from the research being undertaken in the organisation.

An annual report on the efficacy of the research governance processes should be submitted to the Research Governance Committee or the appropriate Committee of the Board for review.

#### Examples of Verification

- Accountability arrangements chart.
- Job description for research governance lead.
- Board Minutes.
- Research Governance Committee Terms of Reference

#### Links with other standards

All standards (generic criterion)

## CRITERION 2

**There is a designated person with responsibility for the management of all research undertaken within the organisation.**

### INFORMATION

#### Source

- Department of Health Social Services and Public Safety (2006) Research Governance Framework for Health and Social Care.
- Department of Health (2001) Governance Arrangements for NHS Research Ethics Committees (*GAfREC*) Department of Health, London.
- General Medical Council (1998) Seeking Patients' Consent: The Ethical Considerations.

#### Guidance

Unless an organisation knows about all the research being undertaken within it, it can not meet its duty of care and other obligations for the effective and safe operation of the organisation.

Systems should ensure research has the explicit permission of the organisation, including research undertaken by students, and that all appropriate other necessary approvals have been obtained. These include:

- Research ethics committee approval
- Medicines & Healthcare Products Regulatory Agency approval for clinical trials involving medicinal products
- Gene Therapy Ethics Advisory Committee approval

The Office for Research Ethics Committees Northern Ireland (ORECNI) working on behalf of the Department of Health and the Central Services Agency provides ethical review of research through Health and Social Care Research Ethics Committees (HSC RECs). It works closely with the National Research Ethics Service which provides, amongst other things, advice on policy and operational matters relating to research ethics committees. Further information can be found at [www.orecni.org.uk](http://www.orecni.org.uk).

Informed consent is at the heart of ethical research. All studies must have appropriate arrangements for obtaining consent, and the ethical review process pays particular attention to those arrangements.

The General Medical Council's guidance – *Seeking Patients' Consent: The Ethical Considerations* sets out the principles of good practice which all registered doctors are expected to follow when seeking patients' informed consent to investigation, screening or research. This includes giving patients sufficient information in order for them to exercise their right to make informed decisions about their care.

Further information on consent can be downloaded from [www.dh.gov.uk/consent](http://www.dh.gov.uk/consent)

#### Examples of Verification

- Evidence that the organisation has a clearly identified R&D management system identifying the authority to approve.
- Evidence that all in the organisation are aware of which individual(s) have responsibility for R&D management in the organisation.
- Organisation charts and distribution of business guides.
- Employment contracts describing research governance responsibilities.
- Evidence of compliance with research governance and related procedures.
- Completeness and accuracy of patient records e.g. project protocol and informed consent forms.

**Links with other standards**

Records Management

**CRITERION 3**

**The organisation ensures financial probity in all matters concerning research governance.**

**INFORMATION****Source**

- Department of Health Social Services and Public Safety (2006) Research Governance Framework for Health and Social Care.

**Guidance**

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

There must be systems in place for the costing, financial management and accounting of all research activity undertaken by the organisation.

**Examples of Verification**

- Study Relevant study approval forms signed off by Director of Finance or delegated representative.
- Trust financial policies and procedures.

**Links with other standards**

Financial management

**CRITERION 4**

**The organisation has a written agreement with research partners documenting the allocation of research responsibilities.**

**INFORMATION****Source**

- Department of Health Social Services and Public Safety (2006) Research Governance Framework for Health and Social Care.
- Model Clinical Trials Agreement for pharmaceutical research.

**Guidance**

A complex array of organisations and individuals may be involved in a research study. It is essential that clear agreements describing allocation of responsibilities and rights are reached, documented and enacted.

Many of these arrangements will 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.

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

The Departments of Health and the Association of the British Pharmaceutical Industry have agreed a model Clinical Trials Agreement (mMCTA) as a standard contractual framework for commercial trials involving NHS/HPSSHSC patients. A specific Northern Ireland version has been developed and should be used by all HSS bodies. Guidance on the agreement and a model agreement can be obtained at [http://www.centralservicesagency.com/display/model\\_clinical\\_trial\\_agreement](http://www.centralservicesagency.com/display/model_clinical_trial_agreement) Work is currently underway to agree similar model agreement for commercial trials involving: contract research organisations; medical devices; and non-commercial trials.

**Examples of Verification**

- Copies of agreements.

**Links with other standards**

None

**CRITERION 5**

**The organisation has arrangements in place to issue HSC honorary contracts to non-HSC researchers.**

**INFORMATION****Source**

- Department for Education and Skills (2001) A Review of Appraisal, Disciplinary and Reporting Arrangements for Senior NHS and University Staff with Academic and Clinical Duties (The Follett Report).
- Department of Health Social Services and Public Safety (2006) Research Governance Framework for Health and Social Care.

**Guidance**

The HPSSHSC operates a system of honorary contracts for research purposes for people employed by other organisations but who carry out research within HPSSHSC organisations that could affect patient care. A range of checks is made on a prospective researcher before an honorary contract can be issued.

Chief Executives of HPSSHSC organisations are accountable for the quality of care and for the environment in which it is provided. Researchers not employed by the HPSSHSC organisation that interact with staff, research participants, or their organs, tissue or data, in a way which has direct bearing on the quality of their care must hold a HPSSHSC honorary contract. Care providers and universities that employ clinical academic staff should make joint arrangements for appointment, supervision and appraisal.

The importance of appropriate lines of accountability for all researchers undertaking studies involving HPSSHSC patients and clinical samples obtained from them is emphasised in the Follett Report. The Report's conclusions on reporting arrangements for academic staff with clinical responsibilities are of particular importance.

Chief Executives of HPSS organisations are accountable for the quality of care and for the environment in which it is provided. Researchers not employed by the HPSS organisation that interact with staff, research participants, or their organs, tissue or data, in a way which has direct bearing on the quality of their care should hold a HPSS honorary contract. Care providers and universities that employ clinical academic staff should make joint arrangements for appointment, supervision and appraisal.

Further information can be obtained from the NHS R&D forum web-site at [www.rdforum.nhs.uk/](http://www.rdforum.nhs.uk/)

An initiative to create a research passport is being piloted at present. The passport will simplify and strengthen honorary contract arrangements and will be introduced in Northern Ireland once the concept is proven.

**Examples of Verification**

- Honorary contracts, or equivalent arrangements which include fulfil research governance requirements.

**Links with other standards**

Human Resources

## CRITERION 6

**All research undertaken within the organisation complies with statutory legislation and guidance**

### INFORMATION

#### Source

- Department of Health Social Services and Public Safety (2006) Research Governance Framework for Health and Social Care.
- Department of Health The (2004) Medicines for Human Use (Clinical Trials) Regulations 2003 2004 Department of Health, London.
- Department of Health (2006) Research Governance Framework for Health & Social Care 2<sup>nd</sup> edition (England).
- In line with the Data Protection Act 1998: The Protection and Use of Patient and Client Information.
- *Health and Personal Social Services Act* (Northern Ireland) 2001.
- <http://www.opsi.gov.uk/legislation/northernireland/acts/acts2001/20010003.htm>
- Human Tissue Act (2004).
- Department of Health (2001) Governance Arrangements for NHS Research Ethics Committees (*GAfREC*) Department of Health, London.
- General Medical Council (1998) Seeking Patients' Consent: The Ethical Considerations.

#### Guidance

All those involved in research with human participants, their organs, tissue or data must be aware of and implement the law, and the basic principles relating to science, ethics, science, information, health and safety, and finance set out in the Research Governance Framework.

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.

The Office for Research Ethics Committees Northern Ireland (ORECNI) working on behalf of the Department of Health (DHSSPSNI) and the Central Services Agency provides ethical review of research through Health and Social Care Research Ethics Committees (HSC RECs). It works closely with the National Research Ethics Service which provides, amongst other things, advice on policy and operational matters relating to research ethics committees. Further information can be found at [www.orecni.org.uk](http://www.orecni.org.uk).

Research involving medicines is regulated under the Medicines Act and the Medicines for Human Use (Clinical Trials) Regulations 2004 and all subsequent amendments. Trials involving medicines covered by Directive 2001/20/EC must be authorised by the Medicines and Healthcare products Regulatory Agency (MHRA). Further information can be accessed from the MHRA website at [www.mhra.gov.uk](http://www.mhra.gov.uk)

Specific regulations govern research within specialist areas, for example, the use of human embryos, ionising radiation or the release of genetically modified organisms.

Informed consent is a fundamental requirement for all research involving HPSSHSC service users. Appropriate arrangements must be in place to obtain informed consent. These arrangements must include giving patients sufficient information in order for them to exercise their right to make informed decisions about their care. Advice on writing Patient Information Sheets and Informed Consent forms is available on the NRES website

[www.nres.npsa.nhs.uk/docs/guidance/Info\\_sheet\\_and\\_consent\\_form\\_guidance.pdf](http://www.nres.npsa.nhs.uk/docs/guidance/Info_sheet_and_consent_form_guidance.pdf)

The Human Tissue Act 2004 makes consent the fundamental principle underpinning the lawful storage and use of body parts, organs and tissue from the living or the deceased. It also covers the removal of such material from the deceased. The purposes for which consent is required are referred to as Scheduled Purposes and these are comprehensively listed within the Act.

Research may involve the use of potentially dangerous or harmful equipment, substances or organisms. The safety of participants, researchers and other staff must be given priority at all times, and health and safety regulations must be strictly observed.

The appropriate use and protection of patient data are 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.

Data collected in the course of research must be retained for a reasonable period to allow further analysis by the original or other research team subject to consent. This retained data will also support monitoring of good research practice by regulatory and other authorities. For example, the Human Tissue Authority regulates the removal, storage, use and disposal of human bodies, organs and tissue for a number of specified health-related purposes including research. These are set out in the Human Tissue Act 2004 which covers England, Wales and Northern Ireland.

The Human Tissue Act 2004 makes consent the fundamental principle underpinning the lawful storage and use of body parts, organs and tissue from the living or the deceased. It also covers the removal of such material from the deceased. The purposes for which consent is required are referred to as Scheduled Purposes and these are comprehensively listed within the Act.

Research involving medicines is regulated under the Medicines Act and the Medicines for Human Use (Clinical Trials) Regulations 2004 and all subsequent amendments. Trials involving medicines covered by Directive 2001/20/EC must be authorised by the Medicines and Healthcare products Regulatory Agency (MHRA). Further information can be accessed from the MHRA website at [www.mhra.gov.uk](http://www.mhra.gov.uk)

Research may involve the use of potentially dangerous or harmful equipment, substances or organisms. The safety of participants, researchers and other staff must be given priority at all times, and health and safety regulations must be strictly observed.

Access to legislation and guidance is essential for the organisation to carry out the statutory duties imposed upon it by law and mandatory duties imposed by the Department of Health, Social Services and Public Safety in Northern Ireland. As a minimum, those involved in the management of research governance should have access to the key references listed on the front page of this standard.

Full text copies of all legislation issued from 1 January 1997 can be downloaded from <http://www.official-documents.co.uk>, which contains information on UK official documents.

### **Examples of Verification**

- Evidence of a defined research approval/management system
- Evidence of all relevant approvals such as ORECNI, MHRA, Gene Therapy Ethics Committee, Administration of Radioactive Substances Advisory Committee
- Evidence of inclusion of data protection etc in HPSS research approval systems.
- Evidence of systems for monitoring research.
- Human Tissue Act 2004 – appointment of Designated Individual and licences held for tissue banks.
- Trial authorisation issued by MHRA.

### **Links with other standards**

Medical Devices Management  
Medicines Management  
Health and Safety

## CRITERION 7

**There is a system in place to record all adverse events arising from any research undertaken by the organisation and staff are made aware of and, where necessary, trained in adverse incident reporting requirements**

### INFORMATION

#### Source

- Department of Health Social Services and Public Safety (2006) Research Governance Framework for Health and Social Care.
- Medicines for Human Use (Clinical Trials) Regulations 2004.

#### Guidance

All staff should be regularly reminded of their responsibilities with regard to adverse incident reporting. This information should also be conveyed to new staff as part of their induction training. Regular reviews should be undertaken to ensure that the procedures are effective and are being followed.

Organisations should record all research related adverse incidents. Organisations providing care must ensure that any research-related adverse events are included in reports 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.

In addition, specific legal requirements exist to report adverse reactions to medicines to the Medicines and Healthcare products Regulatory Agency, the Human Tissue Authority and ORECNI within specified timeframes.

Good Clinical Practice requires the recording and reporting of adverse events. The CRSC provides a programme of GCP training and has also developed standard operating procedures in line with UK 511031 to facilitate the proper recording and reporting of adverse events.

As sponsors of non-commercial research, HSS organisations must ensure they can demonstrate an effective serious adverse event reporting process. In the case of research involving Investigative Medicinal Products, there is a specific statutory requirement to report serious adverse events to the competent authority within specified timelines.

#### Examples of Verification

- Adverse event recording procedures eg Datix or Ulysses.
- Attendance records which demonstrate training of staff in adverse incident reporting
- Staff training records which demonstrate methods of raising staff awareness of specific types of research adverse events that may arise, both within the organisation and elsewhere.
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- Attendance at GCP training courses such as that provided by the CRSC

#### Links with other standards

Risk Management

**CRITERION 8**

**All research undertaken within the organisation has a confirmed sponsor.**

**INFORMATION****Source**

- Department of Health Social Services and Public Safety (2006) Research Governance Framework for Health and Social Care.

**Guidance**

HPSSHSC organisations must ensure that no research with human participants, their organs, tissue or data, begins until an identified sponsor, who understands and accepts the duties set out in this framework, has confirmed it accepts responsibility for that research.

**Examples of Verification**

- Copies of sponsorship agreements.
- Written evidence that sponsors have taken responsibility for each study.

**Links with other standards**

None

## CRITERION 9

**The organisation has a system in place to detect and deal with research misconduct and fraud.**

### INFORMATION

#### Source

- Department of Health Social Services and Public Safety (2006) Research Governance Framework for Health and Social Care.

#### Guidance

There is public and professional concern about potential research misconduct and fraud, though its extent is unknown. Employers of staff engaged in research are responsible for having systems in place to detect and address research misconduct and fraud, and other scientific or professional misconduct by their staff. The Department of Health Social Services and Public Safety will continue to work with others on research misconduct, including plans for a co-ordinating body to support good practice in investigations by relevant stakeholders.

The DHSSPS Counter Fraud Policy Unit has overall responsibility for all work to counter fraud and corruption within the HPSSHSC. In addition, health and social care organisations should themselves ensure that universities and any other organisations with whom they develop local partnerships have appropriate systems for detecting, investigating and addressing fraud by their employees.

In the case of research misconduct, professionals will/may be subject to disciplinary action by their professional bodies. The Council for the Regulation of Health Care Professionals for Healthcare Regulatory Excellence will promote best practice and co-operation between regulatory bodies including the General Medical Council, the Nursing and Midwifery Council and the Health Professions Council ( For example, doctors are responsible to the General Medical Council for their professional conduct as researchers, as well as clinicians. Similarly, nurses, health visitors and midwives are responsible to the Nursing and Midwifery Council and state registered practitioners are responsible to the individual Board of the Health Professions Council for their professional conduct as researchers as well as clinicians. [www.chre.org.uk](http://www.chre.org.uk)). Misconduct by social care professionals will be one of the responsibilities of the General Northern Ireland Social Care Council.

A UK Panel for Health & Biomedical Research Integrity has been established as a joint initiative between Universities UK and the Departments of Health [www.ukrio.org.uk](http://www.ukrio.org.uk). HSS bodies are able to access a code of good practice to support the promotion of research integrity and the effective management of research misconduct. Registered advisors will be available as a source of good-practice advice and as members of local inquiry panels.

#### Examples of Verification

- Evidence of Trust Research Misconduct and Fraud Prevention Policy

- Evidence that staff are aware of the types of research misconduct and fraud that may arise. Evidence of Trust Whistleblowing Policy and disciplinary procedures
- Evidence that monitoring of research governance arrangements is taking place in order to detect and investigate possible fraud and to take appropriate action if either fraud or misconduct is detected.

**Links with other standards**

Human Resources

**CRITERION 10**

**The organisation has systems in place to promote patient and public involvement in all stages of research activity.**

**INFORMATION****Source**

- Department of Health Social Services and Public Safety (2006) Research Governance Framework for Health and Social Care.

**Guidance**

Organisations should promote awareness amongst the clinical research community of the benefits of patient and public involvement (PPI), and encourage researchers to liaise with users, carers and advocacy groups at the earliest possible stage in the planning and development of their research projects.

Participants or their representatives should be involved wherever possible in the design, conduct, analysis and reporting of research. Social care research has a long tradition of the involvement of participants in research. *Involve*, an advisory Group whose remit is restricted to England, aims to promote and support active public involvement in NHS, public health and social care research. *Involve* has established the principle that major advisory bodies in NHS R&D programmes should normally have at least two consumer representatives and further information on this and other aspects of their work can be found at their website: [www.invo.org.uk](http://www.invo.org.uk).

The R&D Office is committed to promoting public awareness of health & social care research and to increase the level of Patient & Public Involvement (PPI) in HPSSHSC R&D. The Office will develop a PPI strategy for the HPSSHSC.

**Examples of Verification**

- Role of consumers identified in research approval processes.
- Policies and procedures. Evidence of PPI consideration in patient documentation
- Evidence of consumer involvement in each study PPI
- Minutes of meetings.
- Copies of correspondence.

**Links with other standards**

None

**CRITERION 11**

**There are systems in place to inform service users and members of the public about research undertaken within the organisation.**

**INFORMATION****Source**

- Department of Health Social Services and Public Safety (2006) Research Governance Framework for Health and Social Care.

**Guidance**

Health and social care research is conducted for the benefit of patients, users, care professionals, and the public in general. There should be free access to information both on 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. Involve, an advisory Group whose remit is restricted to England, have produced guidance aimed at ensuring research findings are accessible to the public and this can be found on their website at: [www.invo.org.uk](http://www.invo.org.uk).

**Examples of Verification**

- Evidence of websites, notice boards, newsletters and publications.
- Requirement for researchers to report back to research subjects on outcomes of research.

**Links with other standards**

None

**CRITERION 12**

**All research conducted by an HSC organisation is appropriately disseminated.**

**INFORMATION****Source**

- Department of Health Social Services and Public Safety (2006) Research Governance Framework for Health and Social Care.

**Guidance**

All those pursuing health and social care research must open their work to critical review through the accepted scientific and professional channels. Once established, findings must be made available to those participating in the research (including the relatives of deceased patients who have consented to the use of organs or tissue in the research) and to all those who could benefit from them, through publication and/or other appropriate means.

Other appropriate means may include the development of these findings commercially (see criterion 13). Intellectual Property Rights (ie Patents, copyright, trademarks etc.) obtained before publication of research results, whether by presentation, journal article or conversation, are required to protect innovations from exploitation by other individuals or organisations.

**Examples of Verification**

- Evidence of research information in newsletters and on websites etc.
- Evidence of a dissemination strategy which are monitored by the organisation.
- Evidence of publications in peer reviewed journals.

**Links with other standards**

None

**CRITERION 13**

**The organisation has systems in place for the appropriate management of intellectual property.**

**INFORMATION****Source**

Department of Health and Social Services and Public Safety (2007) Innovation Policy for Health and Social Care.

Department of Health, Social Services and Public Safety (2006) Research Governance Framework for Health and Social Care.

**Guidance**

Some advances in health and social care need to be developed commercially if they are to be made widely available, such as drugs, new therapies, medical devices, software and training material and aids for disabled people. Innovations are an important asset, which can be of particular value to the HPSSHSC if they are protected as intellectual property (IP).

Successful commercial development often depends upon the protection of IP or commercial confidentiality at critical points in the innovation process. For example, the publication of research findings prior to IP assessment and protection will mean that opportunities to realise the potential benefits may be lost.

IP requires appropriate management to help translate innovations into new products and technologies that could bring about improvements in health and social care practices locally, nationally and globally.

To fulfil the requirements for good research governance, HPSSHSC organisations must ensure that:

- IP is identified and assessed, and where appropriate protected, managed and exploited.
- Employees are aware of the potential for IP arising from both research and clinical practice, and the support available to them.
- Agreements are in place between them and their staff, research funders, other care organisations, universities, industry and any other third parties, about ownership, exploitation and income from any intellectual property that may arise from research conducted by their employees.
- Any material used for research (eg cultures, cell-lines, proteins and other chemicals) is covered under a Material Transfer Agreement.

The Clinical Research Support Centre (CRSC) provides a regional research support capability encompassing all aspects of research, including IP and Innovation/technology transfer. The HPSSHSC Innovations service is delivered through the CRSC, and provides a recognised centre of expertise to which HPSSHSC staff can direct their ideas and innovations.

The service will provide:

- IP and innovation management for all staff.
- Identification, assessment and management of IP assets.
- Development of an innovation culture through training and education.
- Training of staff in the management and development of HPSSHSC IP assets.
- Acceleration of potential products to market and revenue streams.
- Links with the healthcare industry for access to and commercialisation of IP.

Further information can be obtained on the Research and Development Office website at the following link:

[http://www.centraleservicesagency.com/display/rdo\\_research\\_governance\\_innov](http://www.centraleservicesagency.com/display/rdo_research_governance_innov)

### **Examples of Verification**

- Evidence of intellectual property awareness raising.
- Evidence of intellectual property identification, appraisal, protection, development and exploitation.
- Intellectual Property Rights (Patents, trademarks, design rights and copyright).
- Technology transfer (licences, sale, joint ventures, start-up companies).

### **Links with other standards**

Financial management

**CRITERION 14**

**The organisation ensures that all relevant staff are aware of their roles and responsibilities with regard to the research governance framework.**

**INFORMATION**

- Department of Health Social Services and Public Safety (2006) Research Governance Framework for Health and Social Care.

**Guidance**

The roles and responsibilities of:

- The chief investigator, the principal investigator(s) and other researchers
  - The research ethics committee
  - The sponsor
  - The employing organisation and
  - The care organisation/responsible care professional
- are clearly set out in the Research Governance Framework.

The level of information, instruction and training given to staff should be appropriate to the scale of research activity within the organisation and appropriate to their roles within it.

**Examples of Verification**

- Copies of contracts.
- Delegation logs
- Internet access.
- Libraries.
- Training needs analyses.
- Training records.

**Links with other standards**

Human Resources

**CRITERION 15**

**Key indicators capable of showing improvements in research governance and/or providing early warning of risk are used at all levels of the organisation, including the Board, and the efficacy and usefulness of the indicators is reviewed regularly.**

**INFORMATION****Source**

- Department of Health Social Services and Public Safety (2006) Research Governance Framework for Health and Social Care.
- Standards Australia (2004) Risk Management AS/NZS 4360:2004.
- HSS (PPM) 6/2002 AS/NZS 4360: 1999 – Risk Management
- HSS (PPM) 8/2002 Risk Management in the Health and Personal Social Services
- DOA (DFP) 5/2001 – Corporate Governance: Statement on Internal Control.
- HSS (PPM) 3/2002 – Corporate Governance: Statement on Internal Control.
- HSS (PPM) 5/2003 – Governance in the HPSSHSC: Risk Management and Controls Assurance.

**Guidance**

The organisation should develop key indicators, which demonstrate that all stages of the research governance management process are being properly managed effectively and risks are minimised.

Ideally the indicators should be designed to demonstrate improvement in managing the risks associated with research over time. The number of indicators devised should be sufficient to monitor the research governance process. It is not necessarily the case that the Board will use all the indicators. The Board should select those which are useful for ensuring that the internal controls are working satisfactorily and objectives for managing research governance are being met.

One indicator is degree of compliance with this standard. Some other Relevant examples of indicators which organisations may find useful are/may include:

- Number of adverse events involving research.
- Number of key research posts unfilled.
- Number of complaints involving research.
- Number of research staff with up to date training records.
- Percentage of projects subject to monitoring (levels to be set by individual organisations).
- Percentage of projects submitted for publication.

All organisations should be engaged in development and use of key indicators for their own internal performance, but they should also maximise the value of such measures by benchmarking themselves against like organisations, whether those are other HPSSHSC Trusts or others who measure similar processes.

**Examples of Verification**

- Relevant indicators are in place.
- Evidence of usage at all levels
- Monitoring of indicators.

**Links with other standards**

All standards (generic criterion)

**CRITERION 16**

**The system in place for managing research governance, including risk management arrangements, is monitored and reviewed by management and the Board in order to make improvements to the system.**

**INFORMATION****Source**

- Department of Health Social Services and Public Safety (2006) Research Governance Framework for Health and Social Care.
- NHS Executive. Governance in the New NHS: Controls Assurance Statements 2000/2001 and Establishment of the Controls Assurance Support Unit. HSC 2001/005. 2001
- Standards Australia (2004) Risk Management AS/NZS 4360:2004.
- DOA (DFP) 5/2001 – Corporate Governance: Statement on Internal Control.
- HSS (PPM) 3/2002 – Corporate Governance: Statement on Internal Control.
- HSS (PPM) 5/2003 – Governance in the HPSSHSC: Risk Management and Controls Assurance.

**Guidance**

It is the responsibility of the Chief Executive and the Board to monitor and review all aspects of the system for research governance, including:

- Accountability arrangements
- Processes, including risk management arrangements
- Capability
- Outcomes
- Internal audit findings

**Examples of Verification**

- Audit Committee minutes.
- Risk Management Committee minutes.
- Research Committee Minutes.

**Links with other standards**

All standards (generic criterion)

**CRITERION 17**

**The Board should seek independent assurance that an appropriate and effective system of research governance is in place and that the necessary level of controls and monitoring are being implemented.**

**INFORMATION****Source**

- Department of Health Social Services and Public Safety (2006) Research Governance Framework for Health and Social Care.
- Standards Australia (2004) Risk Management AS/NZS 4360:2004. Standards Association of Australia. Strathfield NSW.
- HSS (PPM) 10/2002 – Governance in the HPSS: Clinical and Social Care Governance – Guidance on Implementation.
- HSS (PPM) 3/2002 – Corporate Governance: Statement on Internal Control.
- HSS (PPM) 4/2005 – AS/NZS 4360:2004 Risk Management.
- DAO (DFP) 5/2001 – Corporate Governance: Statement on Internal Control.
- Circular HSS (PPM) 5/2003 – Governance in the HPSS: Risk Management and Controls Assurance.

**Guidance**

Management should consider the range of independent internal and external assurance available, and avoid duplication and omission.

The adequacy of the independent assurance will depend upon the scope and depth of the work performed; bearing in mind its timeliness and the competency of the staff performing it. The level of reliance that can be placed upon such assurances should consider, among other things, the professional standing of the assurer, their level of independence, and whether they could reasonably expect to provide an objective opinion. It is important that any review that takes place results in a report, recommendations for action where necessary, and the retention of sufficient evidence to enable other potential reviewers to rely upon the work already undertaken. The reports should be made to the appropriate sub-committee of the Board.

The CRSC provides a regional Clinical Research Monitoring Service (CRMS) to help HSS bodies gain independent assurance that research is being conducted to the appropriate regulatory and professional standards, facilitate the development of GCP compliant research teams and were appropriately verify the accuracy and completeness of reported clinical trials data. The CRMS can support internal quality assurance by being contracted to undertake site specific monitoring of internal controls processes.

Management arrangements will include an internal audit function, as well as other quality control and assurance functions such as clinical audit. The internal audit function is required to give an opinion to the Board on the adequacy and effectiveness of the overall system of internal control. In doing so, they will seek to work with, and rely on the work of, other review bodies as far as is practical.

The HPSSHSC is given external assurance by such bodies as:

- External auditors, as appointed by the Northern Ireland Audit Office
- Regional Quality and Inspection Authority;

The CRSC provides a regional Clinical Research Monitoring Service (CRMS) to help HSS bodies gain independent assurance that research is being conducted to the appropriate regulatory and professional standards, facilitate the development of GCP compliant research teams and where appropriate verify the accuracy and completeness of reported clinical trials data. The CRMS can support internal quality assurance by being contracted to undertake site specific monitoring of internal controls processes.

- Commission for Health Improvement.

More specific assurance for this standard may be gained from visits by:

- Medicines and Healthcare products Regulatory Agency (MHRA)
- Human Tissue Authority

### **Examples of Verification**

- Schedule of planned reviews.
- Copy of reports.
- Committee minutes.
- Action plans.
- Notes of follow up of actions.
- Evidence file.
- Details of staff involved in the review.
- Medicines and Healthcare products Regulatory Agency (MHRA) inspections
- Human Tissue Authority inspections

### **Links with other standards**

All standards (generic criterion)