NHS
Blackburn with Darwen
Clinical Commissioning Group

NHS
East Lancashire
Clinical Commissioning Group

RESEARCH & DEVELOPMENT POLICY

Developed: February 2017
Review: February 2020

Pennine Lancashire Clinical Commissioning Groups (CCGs) include East Lancashire CCG and Blackburn with Darwen CCG who are members of the Clinical Research Network (CRN): North West. The CCG's Research Policy covers all research that the CCGs are involved in and also research within General Practitioner surgeries.

Policy:	Research Policy
Date Issued:	February 2017
Date to be reviewed:	February 2020

Policy Title:	Research Policy
Supersedes:	New Policy
Description of Amendment(s):	N/A
This policy will impact on:	Pennine Lancs CCGs
Financial Implications:	Decisions may affect commissioning and prescribing costs
Policy Area:	Research, Quality and Medicines Management
Version No:	1
Supported By:	East Lancashire Medicines Management Board
Author:	Dr Lisa Rogan
Document Reference:	
Effective Date:	**February 2017**
Review Date:	**February 2020**
Impact Assessment Date:	20.01.17

APPROVAL RECORD

		Date
Consultation:	Medicines Optimisation Steering Group East Lancashire Medicines Management Board	20.01.2017
Approved by Committees:	Pennine Lancashire Quality Committee	
Acknowledgement	Dorset CCG	

PREFACE

Pennine Lancashire Clinical Commissioning Groups (CCGs) include East Lancashire CCG and Blackburn with Darwen CCG who are members of the Clinical Research Network (CRN): North West. The CCG's Research Policy covers all research that the CCGs are involved in and also research within General Practitioner surgeries.

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RESEARCH POLICY

1. POLICY STATEMENT

1.1 Patient care will be delivered without discrimination, regardless of gender, transgender, race, disability, sexual orientation, age, religion/belief, or cultural practice.

2. INTRODUCTION

2.1 Research is essential to the successful promotion and protection of health and wellbeing, and also to modern, effective health and social care services.

2.2 At the same time, research can involve an element of risk, both in terms of return on investment and sometimes for the safety and wellbeing of the research participants.

2.3 Proper governance of research is essential to ensure that the public can have confidence in, and benefit from, quality research in health and social care.

2.4 The *Research Governance Framework for Health and Social Care* (Department of Health 2001) (RGF) aims to protect the public and improve the overall quality of research in the publicly owned care systems for health and social care. The RGF assigns responsibilities for governance to investigators, other research team members, sponsors, funders, employers of researchers (universities and others), research ethics committees and care organisations.

2.5 The second edition of the Research Governance Framework was published in April 2005. This edition takes account of several developments, including the *UK Medicines for Human Use (Clinical Trials) Regulations 2004* ('Clinical Trial Regulations') and new legislation in human tissue and mental capacity. The National Institute for Health Research (NIHR) established a national framework for local health research management: the NIHR Research Support Services. The framework introduces standard operating procedures for research management that the NIHR expects NHS Organisations to use when undertaking NIHR adopted research studies.

2.6 Pennine Lancashire CCGs are fully committed to the standards set out in the RGF, the Clinical Trial Regulations and other relevant legislation, and to implementing the NIHR Research Support Services framework locally.

3. SCOPE

3.1 This policy covers all commercial and non-commercial activity defined as research, involving the CCG including:

- research involving patients, carers, volunteers and members of staff of the CCG;
- research using patient tissue, organs or data, even if obtained for clinical purposes and/or used for research purposes elsewhere, or obtained from elsewhere but used for research purposes involving the CCG;
- research involving CCG resources, including non-clinical and laboratory-based research;
- research being undertaken as part of an educational qualification.

4. DEFINITIONS

4.1 Research is defined as "the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods". (See NPSA Defining Research Leaflet – X:\Quality & Professional Practice\Department\SUBJECT SPECIFIC CORRES AND DOCS\policies\Research

4.2 Development is defined as the "experimental introduction into practice of alternative clinical procedures or methods of care, together with the simultaneous evaluation of their effectiveness, efficiency or both".

4.3 Audit being defined as a "systematic and critical analysis of the quality of critical care, including the procedures for the diagnosis, treatment and care, the associated use of resources and the resulting outcome and quality of life for the patient" is excluded from this policy.

4.4 Projects which involve "the local assessment of performance and factors which may affect performance within the CCG and are not being conducted as part of a national exercise" are considered as Operational Change in Practice. Whilst the ethics of these may need to be considered they fall outside the scope of this policy.

4.5 Chief Investigator (CI) – 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.

4.6 Investigational Medicinal Product (IMP): A pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial including a medicinal product which has a marketing authorisation but is, for the purposes of the trial, being used or assembled (formulated or packaged) in a way different from the approved form, or being used for an unapproved indication or when used to gain further information about an approved use.

4.7 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 IMPs are known as subjects).

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

4.9 Researchers – those conducting the research.

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

4.11 Sponsor – individual, organisation or group taking 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 the Research Governance Framework that are relevant to the study).

4.12 Student Research – Research performed as part of an educational qualification.

4.13 LRN –Local Research Network.

5. PURPOSE OF THIS OPERATIONAL POLICY

5.1 These principles and guidelines have been developed to ensure that all clinicians and researchers, and the CCGs conform to the requirements of Research Governance. The purpose of this policy is to ensure that the CCG employees and GP practice staff in the Pennine Lancashire CCG area are aware of, and comply with the standards and principles set out in the RGF and the Clinical Trial Regulations.

5.2 The purpose of this Research Policy is to provide a system to ensure all CCG members and staff meet the standard required by the Care Quality Commission, in relation to research which is either led by the CCGs or hosted by the CCGs.

5.3 The following procedures should be followed when conducting any research and development within the CCG.

6. PRINCIPLES

6.1 All research proposals to be registered with the Quality Directorate and must comply with the requirements of Research Governance and the Declaration of Helsinki and ICH GCP ('International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use' (ICH)) developed the E6 Guideline for Good Clinical Practice (1996), known as ICH GCP).

6.2 Research Governance and Management is monitored by the quality directorate

6.3 The administrative responsibilities for the management of research projects prior to local sign-off rests with the Local Research Network.

7. NOTIFICATION AND GOVERNANCE OF THE PROPOSED RESEARCH ACTIVITY

7.1 A description of the notification and governance process is available in Appendix 1

7.2 Research projects must have ethical approval from an appropriate NHS Research Ethics Committee (HRA), where appropriate. For further information please refer to http://www.hra.nhs.uk/research-community/applying-for-approvals/

7.3 Where appropriate, researchers should submit their Integrated Research Application System (IRAS) applications to the CCG.

7.4 The CCG will carry out appropriate governance checks on upon receipt of a valid application.

7.5 All research being carried out within the CCG must comply with the Data Protection Act 1998 and duties of confidentiality. Where consent is not sought prior to accessing patient identifiable information the project must have HRA Confidentiality Advisory Groups Review in addition to HRA ethics review. Project documentation will be reviewed as per local CRN arrangements to ensure compliance. If local researchers believe that an aspect of the research project does not comply with the Data Protection Act 1998 and duties of confidentiality they must contact the Salisbury Research Office and the Caldicott Lead prior to releasing information.

7.6 The Department of Health and the Association of the British Pharmaceutical Industry have agreed a model Clinical Trials Agreement (mCTA) as a standard contractual framework commercial trials involving NHS patients. This generic Clinical Trial Agreement should be used for all Pharmaceutical Industry Sponsored research within NHS organisations and is recommended for all clinical trials.

7.7 All research must be conducted in accordance with the CCG's Standing Financial Instructions and Standing Orders. ACORD guidance is available on the distribution of costs. As far as possible advice on costs will be detailed in the assurance letter and governance report. Research costs must be met by the research funder. Please apply to the Primary Care Research Network (PCRN) or appropriate division lead for support costs. If excess treatment costs are envisaged please contact the R&D Lead for up-to-date advice regarding potential reimbursement before beginning recruitment. GPs should ensure they are satisfied that all costs will be met prior to beginning research activities.

7.8 Clinical Commissioning Programmes will review any research that may incur excess treatment costs, prior to the research commencing.

7.9 Researchers must satisfy CCG HR requirements.

7.10 Projects which have ethical approval may not necessarily receive CCG assurance due to consideration of other factors such as data protection, capacity and finance.

7.11 Research activity, including but limited to preliminary discussions with prospective recruits, shall only be permitted to proceed when it is confirmed that the project complies with the appropriate regulatory framework(s) via the National Institute for Health Research (NIHR) Co-ordinated System for gaining NHS Permission (CSP) assurance checks.

7.12 The Site Principal Investigator must have a letter of assurance authorized by the R&D lead or delegated authority.

7.13 Some governance checks may be delegated to the sponsor and, in exceptional cases, the GP. These are detailed in the letter of assurance and the research governance report.

7.14 GPs must request a copy of the assurance letter when deciding whether to participate in a study.

7.15 If involved with activities that could be classified as research with no letter of reassurance, contact should be made with lead sponsor and/or CCG for clarification purposes.

7.16 Projects will be registered on a central database and copies held within the Quality Directorate within the CCG.

8. RESPONSIBILITIES OF INTERESTED PARTIES

Responsibilities of Research Sponsor

8.1 East Lancashire and Blackburn with Darwen CCGs are not able to act as a research Sponsor.

8.2 East Lancashire and Blackburn with Darwen CCGs will not be delegated any duties associated with the research sponsor.

Responsibilities of care professionals

8.3 Health care staff retain responsibility for the care of their patients or service users, when they are participating in research.

8.4 Before agreeing to their patients or service users and carers being approached, care professionals must satisfy themselves that:

- the chief investigator has the appropriate assurance to proceed with the project, and;

- any research relating directly to the care they provide complies with the RGF.

8.5 Before they enrol patients in a clinical trial, NHS staff should have evidence that the research protocol has the ethical and regulatory approval it needs. They should then take care to follow the approved version of the protocol.

Responsibilities of researchers and collaborators

8.6 Researchers bear the day-to-day responsibility for the conduct of research, and would typically carry out one or more a number of procedures, including but not limited to:

- novel therapeutic interventions, including the administration of an investigational medicinal product or any other physically invasive clinical intervention, such as surgery, which is not already established as routine clinical practice. It also includes the use of any novel mental health intervention;

- novel clinical investigations, including any physically invasive procedure carried out for the purpose of assessment or diagnosis that is not within the routine professional competence of the health care staff that will be involved in the research locally;

- medical devices, including any use of a novel medical device in a clinical investigation;

- clinical monitoring and assessment, including procedures for monitoring the subject and providing data to the Chief Investigator, which are additional to the collaborator's normal clinical responsibilities for monitoring their patients and involve the analysis and interpretation of clinical data in accordance with the protocol;

- qualitative assessments, including the administration of procedures for qualitative assessment (for example, an observational tool or an intrusive interview) that have been designed specifically for the purpose of the research and have the potential to cause significant mental or emotional distress to participants;

- informed consent, including any delegation of responsibility to give information about the research to potential subjects (other than forwarding information provided by the Chief Investigator), to answer their questions, or to take written consent from them.

8.7 Collaborators may be important for the conduct of research locally, but are not defined as local researchers, as they do not carry out the procedures detailed above. Collaborators would typically carry out one or more of a number of procedures, including but not limited to:

- routine investigations, including any physical investigations, such as taking blood or urine samples, that would be within the routine professional competence of the local collaborator;

- administration of simple questionnaires or surveys, which are unlikely to cause any significant mental or emotional distress to participants;

- collection of data or human tissue, including the release of fully anonymised data or tissue samples;

- facilitating the recruitment of participants, including the forwarding of information sheets or recruitment packs, display of advertising material, or promotion of the research in the media.

8.8 Researchers and collaborators are responsible for ensuring that:

- any research they undertake follows the current version of the agreed protocol (or proposal);

- the protocol or proposal has been approved by the CCG;

- helping care professionals to ensure that participants receive appropriate care while involved in research;

- protecting the integrity and confidentiality of clinical and other records and data generated by the research; and

- reporting any failures in these respects, any adverse drug reactions and other adverse events or suspected misconduct through the appropriate systems (please refer to relevant policies).

Responsibilities of the chief investigator

8.9 A senior individual must be designated as the chief investigator for any research undertaken in or through the NHS or social services, or using participants' organs, tissue or data.

8.10 The Chief Investigator takes responsibility for the conduct of the research at a site, and is accountable for this to their employer, and, through them, to the sponsors of the research. They are also directly accountable to the care organisation(s) within which 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 primary responsibility for the design, management and reporting of the study, co-ordinating the investigators who take the lead at each site.

8.11 The completion of any delegated governance checks or conditions of assurance as described in the letter of assurance.

8.12 The research governance responsibilities of the Chief Investigator can be found in Appendix 2.

Responsibilities the GP Practice as an organisation providing care

8.13 It is the responsibility of organisations providing health or social care in England to:

- be aware of all research undertaken in their organisation, or involving participants, organs, tissue or data obtained through the organisation;

- ensure that their patients, service users, carers, and care professionals are provided with information about any research which may have a direct impact on their care, their experience of care, or their work in the organisation;

- ensure that activity is presented as research only if it is being managed formally as research within the provisions of the RGF;

- satisfy themselves that there are adequate arrangements for any research involving their patients, service users and carers, or staff to meet the standards set out in the RGF. In particular, no health or social care research with human participants, their organs, tissue or data, may begin before:

    - an identified sponsor has confirmed it accepts responsibility for that research, and
    - clear, documented agreements are in place about the allocation of responsibilities between all parties involved.

8.14 Care providers remain responsible for the quality of all aspects of the care of their patients or service users and carers, whether or not they are involved in research and whoever conducts or funds that research.

8.15 Researchers not employed by the NHS organisation who interact with individuals in a way which has direct bearing on the quality of their care should hold a NHS honorary contract. Care providers and universities that employ clinical academic staff should make joint arrangements for appointment, supervision and appraisal. The research governance responsibilities of organisations providing care can be found in Appendix 3.

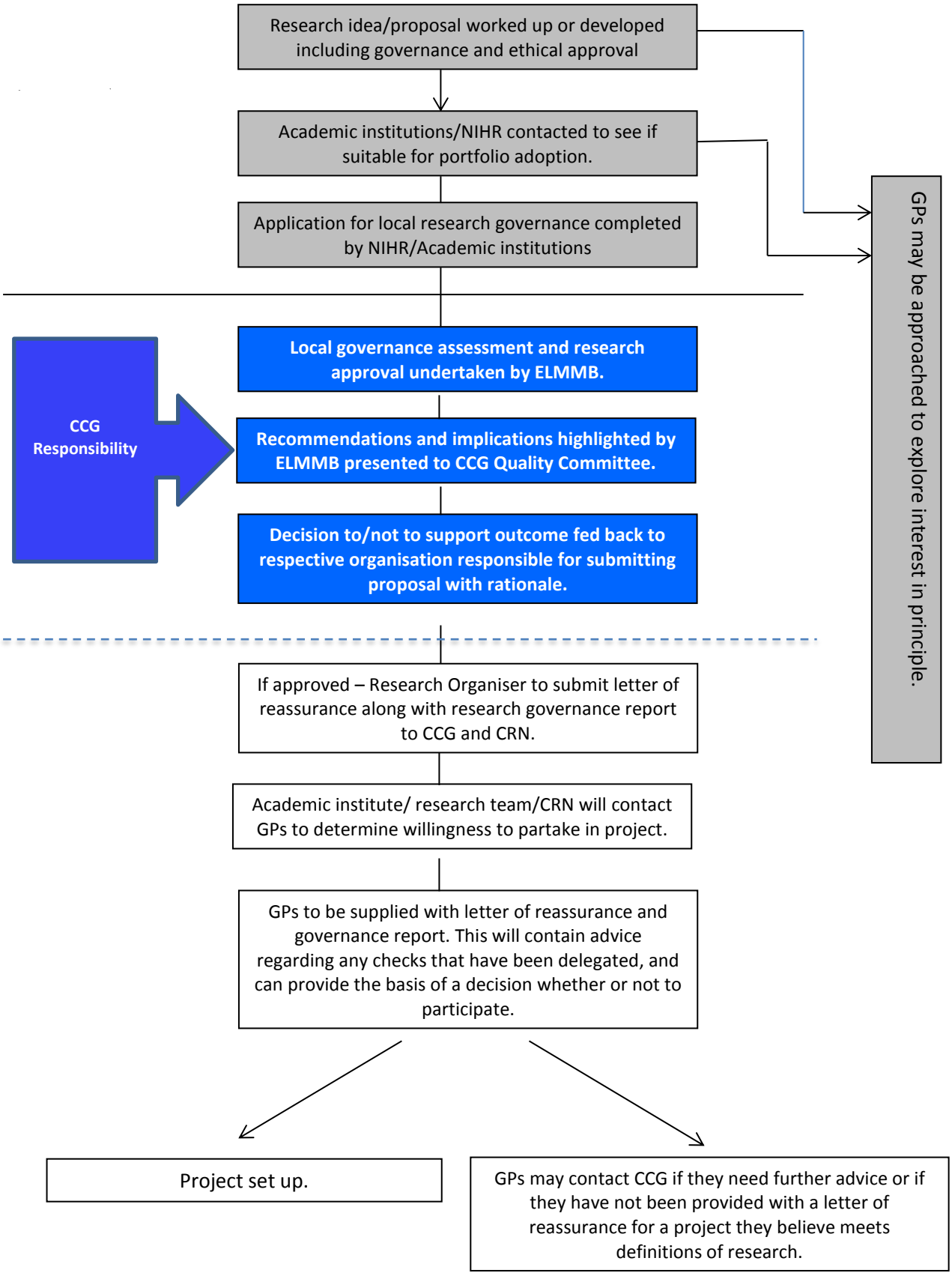
Responsibilities of any organisation employing researchers

8.16 The NHS organisation, as an employer of staff undertaking health and social care research, has responsibility for developing and promoting a high quality research culture in their organisations and for ensuring that their staff are supported in, and held to account for, the professional conduct of research. This will involve careful attention to training, career planning and development, and the use of clear codes of practice and systems for monitoring compliance, dealing with non-compliance or misconduct, and learning from errors and complaints.

8.17 The employing organisation has responsibility for ensuring that researchers understand and discharge legislative responsibilities outlined in the RGF. This may be undertaken for example, through terms of employment, staff handbooks, and training. Employing organisations may take on some or all responsibility for ensuring that a study is properly managed and monitored. Responsibilities taken on by the CCGs will be agreed with the sponsor and the organisation(s) providing care. The sponsor has ultimate responsibility for putting and keeping in place arrangements for the management of a study, and for ensuring there is agreement on appropriate arrangements for monitoring and reporting. Where appropriate, CCGs will ensure that agreements are in place: between them and their employees, 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. The research governance responsibilities of organisations employing researchers may be found at Appendix 4.

8.18 Each individual research study will undergo the appropriate governance checks including an Equality Impact Assessment to ensure and uphold the right of all individuals to participate in high quality research.

Appendix 1- RESEARCH APPROVALS PROCESS IN PENNINE LANCASHIRE CCG



Appendix 2

RESEARCH GOVERNANCE FRAMEWORK FOR HEALTH AND SOCIAL CARE: RESPONSIBILITIES OF CHIEF INVESTIGATOR

Chief investigators must have suitable experience and expertise in the design and conduct of research so that they are able either:

- to undertake the design, conduct, analyses and reporting of the study to the standards set out in the framework, or;

- to lead and manage others with delegated responsibility for some of these aspects.

Chief Investigators are responsible for ensuring the following:

- the research team give priority at all times to the dignity, rights, safety and well-being of participants;

- the study complies with all legal and ethical requirements;

- the research is carried out to the standards in this research governance framework;

- each member of the research team, including those at collaborating sites, is qualified by education, training and experience to discharge his/her role in the study, and their qualifications are documented;

- each investigator in a clinical trial involving medicines is aware of his/her legal duties;

- students and new researchers have adequate supervision, support and training;

- the Chief Executive of the care organisation(s) involved, and/or any other individual(s) with responsibilities within this framework, are informed that the study is planned, and their permission is obtained before the research starts;

- when a study involves participants under the care of a doctor, nurse or social worker for the condition to which the study relates, those care professionals are informed that their patients or users are being invited to participate, and agree to retain overall responsibility for their care;

- when the research involves a service user or carer or a child, looked after or receiving services under the auspices of the local authority, the agency director or her deputy agrees to the person (and/or their carer) being invited to participate, and is fully aware of the arrangements for dealing with any disclosures or other relevant information;

- potential participants and other service users and carers are involved in the design and management of the study whenever appropriate;

- the study is submitted for ethics review and it does not start without a favourable opinion, and the research team acts on any conditions attached to the ethics opinion;

- unless participants or the ethics opinion says otherwise, participants' care professionals are given any information directly relevant to their care that arises in the research;

- unless urgent safety measures are necessary, the research follows the protocol or proposal agreed by the relevant research ethics committee and by the sponsor;

- substantive changes to the protocol or proposal are submitted for ethical review and for the sponsor's agreement. These amendments are implemented only when approved;

- controlled trials are registered, and for clinical trials involving medicines, the research follows any conditions imposed by the licensing authority;

- procedures are kept in place to ensure collection of high quality, accurate data and the integrity and confidentiality of data during processing and storage;

- arrangements are kept in place for the management of financial and other resources provided for the study, including for the management of any intellectual property arising;

- reports on the progress and outcomes of the work required by the sponsor, funders, or others with a legitimate interest are produced on time and to an acceptable standard;

- the findings from the work are opened to critical review through the accepted scientific and professional channels;

- the chief investigator accepts a key role in detecting and preventing scientific misconduct by adopting the role of guarantor on published outputs;

- once established, findings from the work are disseminated promptly and fed back as appropriate to participants;

- there are appropriate arrangements to archive the data when the research has finished, and to make it accessible;

- all data and documentation associated with the study are available at the request of the inspection and auditing authorities.

Appendix 3

RESEARCH GOVERNANCE FRAMEWORK FOR HEALTH AND SOCIAL CARE: ORGANISATIONS PROVIDING CARE

The responsibilities of organisations providing care are to:

- retain responsibility for the quality of all aspects of participants' care whether or not some aspects of care are part of a research study;

- maintain a record of all research undertaken through or within the organisation, including research that students undertake as part of their training;

- ensure patients or users and carers have information on any research that may affect their care;

- ensure legislation relating to research is followed within the organisation;

- require that no research study with human participants for whom the organisation is responsible (or their organs, tissue or data), begins until:

    * a sponsor has confirmed it has taken responsibility;

    * the proposed research has a favourable ethical opinion (and if the study is a trial of a medicine, until there is clinical trial authorisation); and;

    * a person authorised to do so has given written permission on behalf of the organisation providing care;

- ensure written agreements are in place about responsibilities for all research involving an external partner, funder and/or sponsor, including agreement with the university or other employer on supervision of student research;

- maintain links with clinical governance and/or best value processes;

- ensure researchers with no contractual relationship with any NHS body, who are to interact with individuals in a way that directly affects the quality of their care, hold honorary NHS contracts, and that there is clear accountability and understanding of responsibilities;

- put and keep in place systems to identify and learn from errors or failures associated with any research undertaken through or within the organisation;

- ensure that significant lessons learnt from errors or complaints and from internal enquiries are communicated to funders, sponsors and other partners;

Appendix 4

RESEARCH GOVERNANCE FRAMEWORK FOR HEALTH AND SOCIAL CARE: RESPONSIBILITIES OF ORGANISATIONS EMPLOYING RESEARCHERS

Organisations that employ researchers are responsible for:

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