**NHS Education for Scotland**

**Research Governance Policy**

**March 2013**

# Document Information

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| **Author** | Name | Helen Allbutt |
| Job Title | Lead for Research Governance |

# Amendment History

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| **Date** | **Issue No.** | **Details of Change** | **Authorised By:** |
| 19/09/11 | 1 | Initial draft | Helen Allbutt |
| 05/10/11 | 2 | Add timescale to flowchart – Appendix 1Emphasise the benefit of research forum event in summary. Consider inclusion of NES process to deal with external requests for research access | Research Executive Group |
| 03/11/11 | 3 | To be discussed by Business Group with any concerns noted. The policy should apply to much project-related work i.e. a broad interpretation of research should be used. | E&RGC |
| 24/01/12 | 4 | A distributed governance system considered to be a more proportionate and pragmatic approach to the management of NES research activities. | Business Group |
| 20/06/12 | 5 | Policy revised to reflect a distributed model of research governance. No points of challenge were raised at the REG meeting on 20/06/12  | Research Executive Group |
| 15/08/12 | 6 | Set out more explicitly the accountability arrangements and responsibilities for different groups of staff. Modify wording on IP. | E&RGC  |
| 05/09/12 | 7 | Use the SEHD definition of research. Set out where regulation is clear-cut and where there is less explicit guidance. Clearly mark the policy as draft. | Pre-Executive Team meeting |
| 08/10/12 | 8 | Explicitly lay out the various approval processes for research activity | Executive Team meeting 11/09/12 |
| 08/01/13 | 9 | Inclusion of transfer into practice activities under section 3. Section included on indemnity arrangements.  | Executive Team meeting 08/01/13 |
| 22/01/13 | 10 | No change as a result of ET meeting |  |
| 14/02/13 | 11 | Approved subject to minor changes to wording and switching order of sections 8.2 and 8.3. Send to Alice Belcher for final approval. | E&RGC |

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1. **Summary**

New research governance arrangements came into effect in September 2011 which explicitly set out the types of research that require review by a Research Ethics Committee. Research involving NHS staff who are recruited by virtue of their professional role no longer requires REC review except where such research also involves service users or carers. All research activity, however, continues to need management approval from host R&D departments. No explicit guidance has been provided for how organisations should manage research of NHS staff. In these circumstances, ethical review may be undertaken by research ethics committees established by universities or other institutions.

It is the responsibility of each directorate to put in place proportionate research governance processes that align with current UK research governance regulations and the principles and codes of practice set out in the SEHD Research Governance Framework for Health and Community Care. In order to promote an improvement focused culture, research teams should consider participating in interdisciplinary research forum events to receive constructive critique on early stage proposals. It is expected that directorates request final reports of research projects within 6 months following completion and share this information at Research Executive Group meetings. This should allow the NES Educational and Research Governance Committee to ensure there is an appropriate level of oversight for all research activity for which NES is responsible.

**2. What is research governance?**

Research governance is the broad range of regulations, principles and standards of good practice that exist to achieve, and continuously improve, research quality across all aspects of healthcare throughout the UK and worldwide. It applies to all those who fund, host, manage, design, undertake or participate in research regardless of their status.

Research Governance is needed to:

- Safeguard participants in research

- Protect researchers/organisations by providing a clear framework to work within

- Enhance ethical and scientific quality in research

- Minimise research risk

- Monitor research practice and performance

- Promote good research practice and ensure lessons are learned

2.1 There are 6 core principles of good research governance (ESRC, 2010; SEHD, 2006):

* Research should be designed, reviewed and undertaken to ensure integrity, quality and transparency
* Research staff and participants should be fully informed as far as possible about the purpose, methods and intended uses of research, what their participation entails and what risks are involved
* Confidentiality of information supplied by research participants and anonymity of respondents should be respected
* Research participants must take part voluntarily, free from coercion
* Harm to research participants must be avoided in all instances
* The independence of research must be clear and any conflicts of interest must be made explicit
	1. Implementation of these principles involves:
* Organisations having clear, transparent, appropriate and effective procedures in place for ethical review, approval and governance
* The responsibility for conduct of the research resting with the research sponsor / employing organisation and the principal investigator
* The responsibility for ensuring that research is subject to appropriate ethics review, approval and monitoring lying with the sponsor research organisation
* Ethics review being proportionate to the potential risk whether this involves primary or secondary data
* Research being designed in such a way that the dignity and autonomy of research participants is protected and respected at all times

**3. Purpose and scope of policy**

3.1 This policy aims to ensure that NES directorates have systems in place to meet the principles and requirements of research governance and to develop and maintain a quality research culture.

Its purpose is to:

- Ensure all research undertaken by, or on behalf of, NES complies with statutory legislation and guidance

- Ensure that NES research aligns with organisational and NHSScotland priorities

- Provide a framework for the development of a robust research governance processes across NES and with partner organisations

- Set out accountability and responsibilities for research governance

- Ensure that any incidents or risks arising from research governance are identified and managed in accordance with NES policies

- Promote good practice in research across NES

- Support the dissemination of research findings and best evidence

- Support the transfer and exchange of evidence into practice

- Enhance ethical and scientific standards and quality in research

- Ensure that appropriate arrangements are in place to store and dispose of research records

3.2 This policy applies to all research activity undertaken by, or on behalf of, NES including any NES employee who uses NES resources (funding, equipment, premises or staff time). Researchers not employed by NES but who have access to NES resources through an externally commissioned process must also abide by this policy.

3.3 Student projects should be assessed by the same criteria as any other research-related activity. Educational supervisors will need to confirm sponsorship arrangements between NES and academic institutions. Further guidance on student research is available from the National Research Ethics Service website (<http://www.nres.nhs.uk/>).

1. **UK-wide research governance regulations**

4.1 There is a large number of statutes, secondary legislation, policy and guidance documents, research governance frameworks and codes of practice that cover the conduct of research in the UK. Some of the principles and requirements applying to NHS research are clear-cut but others require judgement and interpretation. For example, the types of research that need review by an established NHS Research Ethics Committee (REC) are explicitly set out whilst the organisational arrangements for research which do not require REC review are less specific.

Research which requires REC Review

4.2 A ‘harmonised’ edition of the Governance Arrangements for Research Ethics Committees (GAfREC) was issued by UK Health Departments in May 2011 and came into effect from 1 September 2011. This document clearly states when review by a REC is required within the UK Health Departments’ Research Ethics Service. These include both policy requirements and requirements under legislation which apply across the whole of the UK.

4.3 Under the new GAfREC arrangements, NHS REC review for research, relevant to the purpose of NES, is required for projects which involve:

1. service users and/or carers (past and present)
2. adults (age 16 or over) who lack capacity to consent for themselves (applications must go to Scotland A Research Ethics Committee)
3. prisoners
4. practising midwives conducting a clinical trial
5. confidential patient information

4.4 A proportionate review service is being piloted by several UK Research Ethics Committees to ensure an appropriate level of ethical review for low-risk research studies. Where a research project presents ‘no material ethical issues’ it can be reviewed and approved by a REC sub-committee within 10 working days of receipt of a valid application. In August 2011, the West of Scotland REC became one of the UK pilot sites to provide proportionate review and is available to all researchers working in Scotland.

4.5 There is no longer a requirement to apply for NHS REC review if a project involves NHS staff recruited as research participants by virtue of their professional role. Similarly, research that makes use of, or requires access to, NHS premises or facilities does not need REC review. *However, irrespective of whether REC review is necessary, all research activity will continue to require management permission from the host NHS R&D departments where research is to be undertaken*.

4.6 There is no formal requirement to apply for ethical review under NHS research governance systems to use databases for the purpose of research, and ethical approval would only be required if processing identifiable data without consent. In this context, a research database means a collection of personal data on human subjects for use in research i.e. for analysis. Any application for ethical review therefore should only be made on a voluntary basis. However, researchers must still abide by information governance legislation regarding the collection, storage and use of research information as enshrined in the Data Protection Act 1998 and the Data Protection Order 2000 (see also Good Research Practice Guidelines Oct. 2009 and the NES Information Governance Policy 2011).

4.7 A NHS Research Passport scheme has been set up for researchers who do not have a contractual relationship with the NHS. Researchers need to apply for a honorary NHS research contract prior to the start of their project which can be used across the NHS. Pre-engagement checks on researchers may also be required irrespective of the type of employment contract they hold (see the NES Research Passport Policy Oct. 2010 for further guidance).

 Research activity which does not require REC Review

4.8 No explicit guidelines have been provided in the GAfREC document for how NHS organisations should manage research which does not require formal REC review. In these circumstances, review may be undertaken by research ethics committees established by universities or other institutions. Where NES-funded research is externally commissioned to research teams based within higher education then ethical review of projects could be undertaken through that route. For internally resourced and managed activity then the Research Executive Group might act in that capacity consequent on appropriate support and training. *All research needs approval by a NES Director or their nominated representative before activity starts.*

4.9TheEconomic and Social Research Council’s (ESRC) *Framework for Research Ethics* published in 2010 is cited in the GafREC document as being compatible with wider UK research governance principles and standards. This framework states that organisations should have in place transparent and appropriate procedures for ethical review, approval and monitoring of research activity. A governance system also requires to be sufficiently flexible to accommodate light touch and fuller review where research is of greater scale or represents more risk to the sponsor institution.The ESRC recommends that all research should undergo at least a light touch ethical review (see Research Governance Checklist – Appendix 1) where the potential for risk of harm to participants and others affected by the proposed research is minimal.

**5.** **Definition of research**

5.1 The definition of research in health care is constantly evolving and has been defined differently by a number of organisations. The *Research Governance Framework for Health and Community Care* (SEHD, 2006) describes research in terms of generating new knowledge by the use of systematic and rigorous methods (p. 3). This definition includes studies that aim to generate hypotheses as well as studies that aim to test them. The National Research Ethics Service further elaborates on this description by advising that the primary aim of research is to derive generalisable new knowledge whereas the aim of audit and evaluation is to measure standards of care. Research is to find out what you should be doing; audit and evaluation is to find out if you are doing planned activity and whether it is working (NPSA, 2009). The boundaries between these research-related activities are not always clear and judgement and advice are sometimes required to decide the fit of a project within and between these categories.

**6. Research governance principles and codes of practice for health and community care**

6.1The management of research across NHSScotland is subject to external review through an annual assessment of evidence by the Government’s Chief Scientist’s Office (CSO). The tools and processes used to monitor NHS Board compliance with research governance standards are currently under review and no details have been provided of the new system which is likely to be implemented during 2013. In the meantime all Health Boards are expected to remain compliant with the SEHD Research Governance Framework for Health and Community Care (2006).

6.2 The key features of a quality research culture are set out in that document and include:

*Ethics*: The dignity, rights, safety and well-being should be the primary consideration in any research study. In addition, data protection, informed consent and confidentiality are integral concerns for the research process.

*Science*: Unnecessary research duplication is unethical and all existing sources of evidence must be considered before research is undertaken. Each research proposal should be subject to peer review by those able to offer independent advice on its quality. Where necessary there should be close collaboration with partner organisations in higher education and care to ensure quality and relevance of joint work.

*Information*: Information should be available on all research being undertaken in the organisation held in a central database. There should be provision from a single point on all up-to-date regulatory and advisory documentation relating to research governance together with procedural guidance. Research findings should be published in ways that allow for critical review as well as dissemination to those who could benefit from them.

*Health and Safety:* The safety of research participants and researchers should be paramount and research activity must adhere to health and safety regulations.

*Finance*: Research expenditure should be planned and accounted for and comply with the law laid down for the use of public funds. Consideration must be given to the potential for exploitation of intellectual property.

A quality research culture where there is visible and strong research leadership is essential if researchers and managers are to understand and apply research governance standards, principles and requirements correctly (SEHD, 2006, p.8)

**7. NES structures and processes for research governance**

7.1 It is the responsibility of each directorate to put in place proportionate research governance processes that align with current UK research governance regulation and the principles and codes of practice set out in the SEHD Research Governance Framework for Health and Community Care (2006).

7.2 Each research project that is carried out in the NHS requires a sponsor. This is usually the lead researcher’s employing organisation or the main funder. The sponsor organisation takes on the responsibility for confirming that there are proper arrangements in place to initiate, manage, monitor and finance a project. A template letter has been provided (Appendix 2) to allow directorates to formally authorise approval of a project.

7.3 In order to put in place a quality research culture, directorates must maintain appropriate records and monitor the progress of every research project being undertaken on its behalf. These activities would normally be carried out by directorate research representatives. Approved research projects should be registered prospectively in the central research database (NES Research Register) and updates on approved research activity must be presented at quarterly Educational and Research Governance Committee meetings.

7.4 Participating in interdisciplinary research forum events at an early stage of research preparation is good practice and helps to promote constructive critique of research questions and study design (see Good Research Practice checklist – Appendix 2). This is an integral part of the NES R&D Strategy and should improve research quality and prevent duplication of research activity within NES and partner organisations.

7.5 Directorates must have appropriate project monitoring arrangements in place. If projects are more than one year in duration, it is expected that lead researchers provide an interim project report midway between the start and end of their study. Interim reports should be read by respective directorate representatives with any areas for concern noted and addressed.

7.6 It is expected that directorates receive final research reports within an appropriate timescale (within 6 months) following completion of a study. Research information on final reports should be shared and disseminated at research meetings.

**8.** **Accountability arrangements and responsibilities**

8.1 Overall accountability for the conduct of research lies with the Chief Executive of NES. This responsibility is delegated to the Director of Educational Development for the development and implementation of NES Research Governance systems and procedures. Leaders of NES directorates and their designated research representatives are accountable for their directorate research governance processes to ensure that research is properly designed, well-managed, monitored and reported.

8.2 The Education and Research Governance Committee has responsibilities for overseeing the executive and operational functions of research governance within NES. These are:

* To be assured of the effective management of NES research projects and programmes
* To receive an annual research governance compliance report from each directorate about how they approve, manage and disseminate research activity.
* To oversee the development and implementation of strategies, policies, structures and processes relating to research
* To promote collaboration within NES and with external agencies in relation to research, educational development and evaluation
* To advise the NES Board on matters relating to research
* To report to the NES Board on outcomes from NES research and development programmes
* To monitor approval processes for the disbursement of educational research funds
* To request audits as necessary to ensure directorates are complying with UK-wide research governance regulations

8.3 The Director of Educational Development has executive responsibilities for research governance within NES. These are:

* Supporting the Chief Executive in submitting evidence and reporting to the Scottish Government’s CSO of NES’ compliance with research governance standards
* Ensuring directorate research representatives have access to information on guidelines about UK research governance procedures and regulatory documentation
* Informing directorate research representatives of changes to regulation relating to research activity
* Taking action if research misconduct or fraud is suspected

8.4 The Educational and Research Governance Executive Group has collective responsibility for ensuring that:

* They are aware of all research being conducted within or on behalf of NES
* NES research activity conforms to UK-wide research governance regulations
* Systems are in place to identify best research practice and action is taken to remedy any shortfall
* There is appropriate oversight of the implementation of the NES R&D Strategy
* An environment conducive to effective research practice is established and maintained
* Research collaborations are identified and actively promoted across NES and with partner agencies
* Communicating research activity to internal and external audiences through various media
* The impact of research strategies, systems, policies and procedures are evaluated across NES

Directorate research representatives are responsible for:

* Approving research projects within their directorate and making judgements with regard to the types of approval required.
* Registering research projects to be conducted and providing timely updates to the Research Executive Group whilst studies are in progress
* Ensuring research within their directorate has passed the necessary quality assurance measures such as peer and ethical review, Health Board approval and other associated requirements before a project commences
* Ensuring research activity within their directorate is monitored and reported effectively by submitting an updated research register on a quarterly basis
* Ensuring that the E&RGC has oversight over directorate research structures and processes for governing research by submitting an annual research governance compliance report
* Ensuring research activity within their directorate represents value for money

8.5 Researcher responsibilities:

Each researcher is accountable for their own practice and for abiding by UK legislation and guidance of good research practice. The researcher is responsible for:

* Notifying the designated directorate research representative of any research they are planning to undertake
* Formally registering their research project with the designated directorate research representative
* Ensuring there is approval for all research for which they have a duty of care including directorate and REC approval and local R&D management approval
* Ensuring they are suitably qualified and competent to undertake the research
* Adhering to the approved research protocol
* Complying with legal and ethical requirements and guidance including the storage and disposal of raw research data
* Ensuring participants’ welfare while in a study
* Ensuring effective arrangements are in place for the financial management of the research
* Reporting any adverse incidents connected to the research
* Disseminating and publicising their work with appropriate guidance

**9. Indemnity arrangements for healthcare research**

9.1 **The NHS is vicariously liable for actions of its employees through NHS indemnity via the CNORIS scheme in NHSScotland. This covers NHS employees, patients and healthy volunteers against harm caused by negligence.  Because participants in research can be harmed through non-negligent conduct i.e. 'no fault' harm, research which poses substantial risk should be reviewed by an external party such as a Scientific Officer or a REC. In certain cases, a research ethics committee might ask for cover to be provided against 'no fault' harm.**

**9.2 The SEHD *Research Governance Framework* requires that insurance and indemnity arrangements are in place before research starts. 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.**

9.3 **For research undertaken by non-NHS researchers, independent insurance arrangements should be made.  GPs, Dentists, Pharmacists, Optometrists and other independent practitioners (unless they are salaried NHS employees) are not normally covered by NHS indemnity.  Cover in these cases is usually sought through professional bodies such as the Medical Defence Union etc.**

**9.4 University researchers who are not ‘clinical academics’ require a research passport in order to qualify for NHS indemnity.**

**10. Project completion, storage and retention of research data**

10.1 Lead researchers will be held responsible for the accuracy, completeness and security of all the records produced during a research project. Research data are inclusive of, but not limited to, all primary data sources: completed questionnaires, consent forms, audio and video recordings. Confidential records containing personal information must be stored in secure facilities in locked rooms or cupboards in accordance with the standards set out in the NES Information Governance Policy 2011. Electronic records should be kept in line with NES IM&T guidelines and be protected by passwords and other security devices.

10.2 Research records containing personal data must be handled in accordance with the Data Protection Act 1998. Principle 5 of this Act states that ‘personal data processed for any purpose or purposes shall not be kept for longer than is necessary for that purpose or those purposes’. This principle should be adhered to as far as possible although personal data processed for the purpose of research may be kept indefinitely. The proposed retention period of research records should be made explicit where the basis for access is by consent. Some research sponsors specify the requirements for retention of specific categories of research from completion of a project; the ESRC requests 10 years, the MRC states a minimum of 10 -20 years depending of the type of study. Research is a complex activity and retention of records depends upon assessing the risks of not having access to evidence of decisions made, actions taken and results produced during the course of a project as well as the benefits of retaining records of this evidence for NES and for partner organisations.

10.3 In determining retention records for a longer period than five years from completion of NES-funded research, lead researchers should consider whether records should be retained to support intellectual property, whether research has been linked to inquiries such as allegations of scientific or financial misconduct or if the research has been controversial or ground-breaking. If none of these conditions apply, then primary research records should be destroyed when agreed retention periods expire. The date of destruction should be recorded in the central register of research.

**11. Involvement of research users and the public in research**

11.1 Users of research (staff groups, educational advisers, students, service users or their representatives) should be involved wherever possible in the design, conduct and reporting of research. Research should reflect the diversity of society and where relevant take account of age, gender, sexual orientation, race, culture and religion in design, conduct and dissemination of findings.

11.2 There should be access to information on the research being conducted and on the findings of research once these have been subjected to appropriate review.

11.3 The appropriate use and protection of research data, particularly patient information, is of paramount importance. All individuals involved in research must be aware of their legal and ethical duties and pay particular attention to the security of systems for ensuring confidentiality of personal information. All relevant NES and governmental polices and procedures for ensuring research governance must be complied with e.g. Data Protection Act (1998), NES Research Governance Policy, NES Information Governance Policy, NES Mobile Computing Policy, IM&T Security Policy and the requirements of Caldicott.

**12. Finance and intellectual property**

12.1 All researchers must comply with the procedures of NES’ standing financial instructions in planning and accounting for all expenditure associated with research activity.

12.2 There is a responsibility on NHS organisations to exploit intellectual property (IP) generated by research activity. Researchers in conjunction with directorate research representatives should seek to identify any potential for IP at the outset of research projects and ensure that the standard contract terms for IP in the NES contract templates are adhered to.

12.3 It is assumed that NES has exclusive rights to IP made or created by researchers in respect of work for which they are under contract to NES. Commercial exploitation of research activity must be undertaken only with appropriate agreements in place, based on independent advice, and approved by the Director of Finance and the appropriate Director (see the NES Intellectual Property Policy Nov. 2010 for further guidance).

**13. References and sources**

Chief Scientist Office (No date) Extension to Existing Policy Framework: Policy Framework for Managing Intellectual Property in the NHS:

http://www.cso.scot.nhs.uk/IP/GuidancePart2.doc

DoH (2011) Governance arrangements for research ethics committees (GAfREC)

<http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_126474>

Economic and Social Research Council (2010) Framework for Research Ethics

<http://www.esrc.ac.uk/_images/Framework_for_Research_Ethics_tcm8-4586.pdf>

Integrated Research Application System: <https://www.myresearchproject.org.uk/Signin.aspx>

National Research Ethics Service website: <http://www.nres.nhs.uk/>

NHS R and D Forum: <http://www.rdforum.nhs.uk/workgroups/primary/pcinfoguide/introduction.htm>

NPSA (2009) National Research Ethics Service - Defining Research

<http://www.nres.nhs.uk/applications/is-your-project-research/>

Scottish Executive Health Department (2006) Research Governance Framework for Health and Community Care. 2nd Edition

http://www.cso.scot.nhs.uk/publications/ResGov/Framework/RGFEdTwo.pdf

**Appendix 1**

**Research Governance Checklist**

This checklist has been drawn up to help directorates identify whether studies may require review by a NHS Research Ethics Committee.

Project title:

Lead researcher details:

Role:

Email address:

Contact address:

Telephone number:

NES accountable officer:

Duration of study:

Funding source:

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | Y | N |
| 1. | Does the study involve participants who are potentially vulnerable or unable to give informed consent? (e.g. service users / carers, children, people who lack capacity) | 🖵 | 🖵 |
| 2. | Will the study require the co-operation of a gatekeeper for initial access to the groups or individuals to be recruited? (e.g. members of self-help group, residents of nursing home) | 🖵 | 🖵 |
| 3. | Will it be necessary for participants to take part in the study without their knowledge and consent at the time? (e.g. covert observation of people in non-public places) | 🖵 | 🖵 |
| 4. | Will the study involve discussion of sensitive topics (e.g. sexual activity, drug use, violence at work)? | 🖵 | 🖵 |
| 5. | Will the study involve any invasive, intrusive or potentially harmful procedures of any kind? | 🖵 | 🖵 |
| 6. | Could the study induce psychological stress or anxiety or cause harm or negative consequences beyond the risks encountered in normal life? | 🖵 | 🖵 |
| 7. | Will the study involve prolonged or repetitive testing? | 🖵 | 🖵 |
| 8. | Will the research involve medical devices (products, other than medicines, used in healthcare for diagnosis, prevention, monitoring or treatment of illness or disability)? | 🖵 | 🖵 |
| 9. | Does the research involve members of the public in a research capacity (participant research)? | 🖵 | 🖵 |

***If the answer to any of the above questions is ‘Yes’ then an ethical review via a UK Research Ethics Committee may be required.***

**Appendix 2**

**Suggested Sponsorship Letter**

**(Use local NES headed paper)**

Address

Date

Dear

**Research Study Title:**

NHS Education for Scotland agrees to be the Sponsor for this project under the requirements of the Governance Arrangements for Research Ethics Committees (GAfREC) issued by UK Health Departments in May 2011.

NHS Education for Scotland accepts the responsibility to be satisfied that;

* The research proposal respects the dignity, rights, safety and well-being of participants and the relationship with care professionals;
* An appropriate process of independent expert review has demonstrated that the research proposal is worthwhile, of high scientific quality and good value for money;
* Where appropriate, a NHS ethics committee has given a favourable opinion;
* The chief investigator and other key researchers 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;
* There is written agreement about the arrangements for the management and monitoring of the study;
* Arrangements are in place for the sponsor and other stakeholder organisations to be alerted if significant developments occur as the study progresses, whether in relation to the safety of individuals or to scientific direction;
* Agreement has been reached about compensation in the event of harm to research participants 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;
* Arrangements will be made to assist any enquiry, audit or investigation related to the work.

Yours sincerely

Name

Designation

**Appendix 3**

**Good Research Practice Checklist**

This checklist has been drawn up to help directorates identify the key points of good practice in research

|  |  |
| --- | --- |
| **Before conducting research:** | **Tick** |
| Is your research question appropriate and designed to add to whatever is already known about a topic or the methods for researching that topic?  |  |
| Have equality and diversity issues been fully addressed in the design, method(s) to be used and sampling frame?  |  |
| Is your research design appropriate for the question(s) being asked?  |  |
| Do you have access to all the necessary skills and resources to conduct the research?  |  |
| Does your research comply with all legal and ethical requirements and other applicable guidelines including those from other organisations and/or countries if relevant?  |  |
| Does your research comply with all requirements of legislation and good practice relating to health and safety?  |  |
| Has your research undergone scientific and ethical review and received necessary approval from a NHS research ethics committee and/or local Health Board R&D departments? Does it have NES Director approval? |  |
| Have you made provision for all necessary monitoring and audit?  |  |
| Are you compliant with financial contracts and guidelines relating to the project?  |  |
| Have you identified any potential for intellectual property arising from the research and is ownership made explicit in the contract? |  |
| Have you reached an agreement with your research colleagues relating to publication and authorship?  |  |
| Have you reached an agreement relating to collaborative working, if applicable?  |  |
| Have you agreed the roles of researchers and responsibilities for management and supervision?  |  |
| Have all conflicts of interest relating to your research been identified and resolved?  |  |
| Are you aware of the guidance from all applicable organisations on misconduct in research? |  |

|  |  |
| --- | --- |
| **When conducting research:** |  |
| Are you following the agreed research design for the project?  |  |
| Have any changes to the agreed research design been reviewed and approved?  |  |
| Are you following best practice for the collection, storage and management of data?  |  |
| Are agreed roles and responsibilities for management and supervision being fulfilled?  |  |
| Is your research undergoing all necessary monitoring and audit?  |  |

|  |  |
| --- | --- |
| **When finishing research:** |  |
| Has your research and its findings been reported accurately, honestly and promptly?  |  |
| Have equality and diversity issues (in addition to location, socio-economic status and care-giving responsibilities of research participants) been appropriately covered in the analysis and interpretation of results?  |  |
| Have all contributions to the research been appropriately acknowledged?  |  |
| Have agreements relating to intellectual property, publication and authorship been complied with?  |  |
| Has feedback and dissemination of research covered practice and learning networks and taken account of the needs of different research user groups?  |  |
| Have research data been retained in a secure and auditable form and for the required duration?  |  |
| Has your research complied with all legal, ethical and contractual requirements?  |  |