1 Introduction

1.1. The Newcastle upon Tyne Hospitals NHS Foundation Trust (the ‘Trust’) recognises the importance of research to the successful promotion and protection of health and wellbeing. However, 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. Therefore, proper governance of research is essential to ensure that the public can have confidence in, and benefit from, high 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.

1.2. The Research Governance Framework for Health and Social Care was developed by the Department of Health as a framework for the governance of research and applies to all research that relates to the responsibilities of the Secretary of State for Health. This includes clinical and non-clinical research; research undertaken by NHS or social care staff using the resources of health and social care organisations; and any research undertaken by industry, charities, research councils and universities within the health and social care systems that might have an impact on the quality of those services.

1.3. All NHS Organisations must comply with the Research Governance Framework (RGF) when getting involved with any research. Research Governance is one of the core standards for health care requiring health care organisations to have systems to ensure the principles and requirements of the framework are consistently applied. Health care organisations have to take this standard into account in discharging their duty of quality under Section 45 of the Health and Social Care (Community Health and Standards) Act 2003.

2 Scope

2.1. This policy sets out the requirements for all research within the Trust to ensure that research activity complies with the principles of the RGF and satisfies the Research Governance domain of the core standards for healthcare required by the healthcare regulator the Care Quality Commission.
2.2. This policy applies only to research activity where research is defined as:

“… the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods” (RGF, para 1.10, pg.3)

The policy does not apply to audit or service evaluations. For guidance on the differentiation between research, audit and service evaluations see the Newcastle Joint Research Office (NJRO) website: http://www.newcastlejro.org.uk/research-governance/is-my-project-research/

2.3. This policy applies to all research activity involving the Trust including:

- Research where the Trust is a lead organisation or Sponsor
- Research where the Trust is a participating site in research
- Research where participants are patients, carers, volunteers and members of Trust staff
- Research using patient tissue, organs or data
- Research taking place on Trust premises
- Research involving Trust resources
- Research that is non-clinical or laboratory based
- Research being undertaken as part of an educational qualification

3 Aims

The aim of this policy is to set out a framework for the conduct of clinical research within the Trust.

4 Duties and Responsibilities

4.1 Chief Executive

The Chief Executive has overall responsibility for the strategic direction and operational management of the Trust and takes overall responsibility for this policy.

4.2 Associate Medical Director for Research & Development

The Associate Medical Director for Research & Development (R&D) is the Lead for Clinical Research and delivery of the R&D strategy. This responsibility is delegated by the Medical Director as the Executive Lead for the Trust.
4.3 R&D Approvals Committee

The R&D Approvals Committee has responsibility for reviewing and risk assessing all clinical research projects prior to confirming NHS Management Permission.

4.4 The R&D Department

The R&D Department has responsibility for ensuring all research projects conducted within the Trust are done so in accordance with all applicable legislation and guidance including the RGF. This is achieved through risk assessment of all new projects, audit of existing projects and provision of guidance for researchers.

4.5 Researchers

Everyone involved in research with human participants, their organs, tissue or data is responsible for knowing and following the law and the principles of good practice relating to ethics, science, information, health and safety, and finance set out in the RGF. All those involved in research also have a duty to ensure that they and those they manage are appropriately qualified, both by education and experience, for the role they undertake in relation to any research.

5 Definitions

5.1 Advanced Therapy Medicinal Products (ATMP)

Is defined as any of the following medicinal products for human use:
- a gene therapy medicinal product
- a somatic cell therapy medicinal product
- a tissue engineered product

5.2 Advanced Therapy Investigational Medicinal Products (ATIMPs)

An ATMP as defined in Article 2(1) of Regulation 1394/2007\(^2\) which is tested or used in a clinical trial (in accordance with Article 2(d) of Directive 2001/20/EC\(^3\)

5.3 Chief Investigator

The person who takes overall responsibility for the design, conduct and reporting of a study if it is at one site; or if the study involves researchers at more than one site; the person who takes primary responsibility for the design, conduct and reporting of the study, whether or not that person is an investigator at any particular site (RGF, DoH, 2005).
5.4 Clinical Trial of an Investigational Medicinal Product (CTIMP)

A clinical trial that is within the scope of the UK Medicines for Human Use (Clinical Trials) Regulations 2004⁴ and subsequent amendments⁵, ⁶, ⁷. An investigation in human subjects, other than a non-interventional trial, intended:
   a) to discover or verify the clinical, pharmacological and/or other pharmacodynamics effects of one or more medicinal products,  
   b) to identify any adverse reactions, or  
   c) to study absorption, distribution, metabolism and excretion, with the object of ascertaining the safety and/or efficacy of those products.

5.5 Employing Organisation

The organisation employing the CI, investigators or other researchers. Employers remain liable for the work of their employees and should:
   • ensure researchers understand and discharge their responsibilities.  
   • ensure studies are properly designed and submitted for independent review.  
   • ensure studies are managed, monitored and reported as agreed according to the protocol.  
   • provide written procedures, training and supervision  
   • take action if misconduct or fraud is suspected.

The organisation employing the CI normally holds the contract or grant agreement with the funder of the study. Organisations holding contract with funders remain responsible for the management of the funds provided (DH 2005).

5.6 Good Clinical Practice (GCP)

GCP is a set of internationally recognised ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting CTIMPs that involve the participation of human subjects. Compliance with GCP provides assurance that the rights, safety and wellbeing of trial subjects are protected and that the results of clinical trial are credible and accurate.

5.7 Intellectual Property (IP)

IP can be described as the novel or previously undescribed output of any intellectual activity. It has an owner and can be bought, sold or licensed and must be adequately protected. It can include inventions, industrial processes, software, data, written works, designs and images.
5.8 Investigational Medicinal Products (IMPs)

A pharmaceutical form of an active substance or placebo being tested, or to be tested, or used, or to be used, as a reference in a Clinical Trial, and includes a medicinal product which has a marketing authorisation but is, for the purposes of the trial:
   a) used or assembled (formulated or packaged) in a way different from the form of the product authorised under the authorisation
   b) used for an indication not included in the summary of product characteristics under the authorisation for that product, or
   c) used to gain further information about the form of that product as authorised under the authorisation.

5.9 NHS Management Permission

Often described as R&D Approval, this is the written management permission granted by an NHS Trust to allow researchers to undertake research which involves patients, staff or facilities/premises of that Trust.

5.10 Organisation Providing Care

The organisation responsible for providing health or social care to patients and/or service users and carers participating in a study. Health and social care organisations remain liable of the quality of care, and for their duty towards anyone who might be harmed by a study (DH 2005). The Organisation Providing Care is responsible for:
   • Arranging for an appropriate person to give permission for research involving their patients, service users, carers or staff, before the research starts.
   • Ensuring any such research is conducted to the standards set out in the RGF.
   • Ensuring there is evidence of ethical review before recruitment to any research that affects their duty of care.
   • Before recruitment to trials with medicines, must ensure there is evidence of a positive ethical opinion and a Clinical Trials Authorisation.
   • The care of participants to whom they have a duty of care.

5.11 Principal Investigator (PI)

The leader responsible for a team of individuals conducting a study at a site (DH 2005).

5.12 Researchers

Those conducting the research. (DH 2005)
5.13 Research Ethics Committee (REC)

A 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. (DH 2005)

5.14 Research Sponsor

Individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a study. A group of individuals and/or organisations may take on sponsorship responsibilities and distribute them by agreement among the members of the group, provided that collectively, they make arrangements to allocate all the responsibilities in the research governance framework that are relevant to the study. (DH 2005)

5.15 Responsible Care Professional

Doctor, nurse, social worker or other practitioner formally responsible for the care of participants while they are taking part in the study. (DH 2005)

6 Requirements for Trust NHS Management Permission

6.1. All research taking place within the Trust must have Trust NHS Management Permission before the commencement of any research activity. The only official notification of Trust NHS Management Permission is a letter signed on behalf of the Trust by the Research Governance Manager of the R&D Department or a Delegate Signatory. The process of applying for NHS Management Permission is available on the NJRO website: http://www.newcastlejro.org.uk/research-governance/nhs-permissions/th-nhs-permission-process/

6.2. A risk assessment of each proposed research project will be undertaken. The risk assessment will be based on the principles and standards of the RGF with evidence required of all other regulatory approvals before NHS Management Permission is finalised. Low risk research with no issues identified may be approved by a Research Management & Governance Manager. All other research will be presented for discussion at one of the fortnightly meetings of the R&D Approvals Committee (see Appendix 1 for the Terms of Reference of the Committee). The main areas for assessment will be as follows:

6.2.1. Research Sponsorship

The RGF requires all research within the NHS or social care services in England to have an identified Research Sponsor. Both the Trust and Newcastle University (the University) have registered with the Department
of Health as Research Sponsors and the arrangements that have been agreed for research involving the Trust and/or the University are detailed in Appendix 2. It must be noted that the Trust and University never co-sponsor studies together or with external organisations, unless all other options have been considered/exhausted.

Investigators should refer to the relevant Standard Operating Procedure (SOP) when approaching the Trust to act as sponsor:

- for CTIMPs see SOP-JRO-17 ‘Obtaining Trust Sponsorship of a CTIMP’ or
- non-CTIMPs see SOP-JRO-11 ‘Obtaining Trust Sponsorship for non CTIMP’

Prior to confirming Trust sponsorship of any CTIMP, a thorough risk assessment must be performed and approved by R&D in accordance with the relevant JRO SOP.

For commercially initiated research, the commercial company would be expected to act as research sponsor. If the sponsor is outside the United Kingdom, the sponsor must have a Legal Representative within the United Kingdom (see below for specific requirements for studies which fall within the Medicines for Humans Use (Clinical Trials) Regulations 2004.

6.2.2. Ethical Review

The dignity, rights, safety and wellbeing of participants must be the primary consideration in any research study. The Department of Health requires that research involving patients, service users or volunteers, or their organs, tissue or data is reviewed independently to ensure it meets ethical standards.

For all research which falls within the remit of the Governance Arrangements for Research Ethics Committees (GafREC) paragraph 2.3.2., review from a recognised NHS REC is required.

Applications for NHS REC review are prepared via the Integrated Research Applications System (IRAS) at https://www.myresearchproject.org.uk

Evidence of full favourable opinion from an NHS REC, including confirmation that the participant information sheet and informed consent form have been reviewed, is required before the Trust will grant NHS Management Permission.
6.2.3. Scientific Review

All existing sources of evidence, especially systematic reviews, must be considered carefully before undertaking research. Research which duplicates other work unnecessarily, or which is not of sufficient quality to contribute something useful to existing knowledge, is unethical.

Every proposal or protocol must be subjected to review by relevant experts who are able to offer independent advice on its quality. It is the research sponsor’s responsibility to ensure adequate scientific review (also known as peer review) is in place which is proportional to the scale of the research. For externally funded research, for example from a research council or charity, it is expected that scientific review would have been undertaken by the funder as part of the review of the application for funding. For commercially sponsored projects, it is the responsibility of the commercial sponsor to arrange scientific review. For student projects, the peer review processes of the university involved should normally be adequate.

For self-funded or own account research where the Trust is asked to act as Research Sponsor, the R&D office will arrange an independent scientific review.

Evidence of a favourable scientific review must be in place before NHS Management Permission will be granted.

6.2.4. Finance/Evidence of Funding

Financial probity and compliance with the law and with the rules set out by HM Treasury for the use of public funds are as important in research as in any other area. There must be transparency and accountability of all research income and expenditure.

When considering a project for NHS Management Permission, the Trust must satisfy itself that all costs for the research are fully covered. There must be evidence that funding has been secured for the research project before R&D can consider processing an application for NHS Management Permission.

The Attributing the Costs of Health and Social Care Research and Development (AcoRD) makes it clear that funding for commercially contracted research (funded and sponsored by a commercial company) should cover the full cost incurred, including appropriate Trust overheads. For all commercial research within the Trust there is also a non-refundable R&D Fee.
6.2.5. Conducting Clinical Trials of CTIMPs and ATIMPs

There is a strict legal framework within which CTIMPs and ATIMPs must be conducted. The EU Clinical Trials Directive and GCP Directive (transposed in UK Law through the Medicine for Human Use (Clinical Trials) Regulations 2004 (SI 1031) and Amendment Regulations 2006 (SI 1928), state that clinical trials must be carried out to the principles of GCP based on Articles 2 to 5 of the GCP Directive. ATIMPs have additional Regulatory requirements which must also be adhered to (transposed in UK Law through the UK Statutory Instrument 2010 (1882) The Medicines for Human Use (Advanced Therapy Medicinal Product and Miscellaneous Amendments) Regulations 2010).

Clinical Trials legislation states it is against the law to start or conduct, or to recruit participants to a clinical trial involving a medicinal product until there is a favourable opinion from an NHS REC and a Clinical Trials Authorisation from the licensing authority, the Medicines and Healthcare products Regulatory Agency (MHRA).

Research Sponsors have specific legal duties under the Medicines for Human Use (Clinical Trials) Regulations 2004. Regulation 3 defines options for sponsorship requiring that where the research sponsor is outside of the European Community then the sponsor must identify a Legal Representative within the European Community.

It can be difficult in some situations to determine if a particular study falls within the Medicines for Human Use (Clinical Trials) Regulations 2004 as the term ‘medicines’ embraces all kinds of medicinal products, including pharmaceutical and biological medicines, vaccines, herbal remedies and homeopathic products. The regulations also apply to products which already have a marketing authorisation but are used or assembled in a way different from the authorised form, or when used in an unauthorised indication, or to gain further information about the authorised form.

It is vital to know when preparing a bid for funding whether a study is a CTIMP or ATIMP as this will have significant impact on the funding required for the management and monitoring of the study. If an investigator is unsure whether their study is a CTIMP or ATIMP and this study involves the Trust acting as Research Sponsor, then any approach to the MHRA regarding the status of the study must be directed through the R&D Department.
Managing IMPs in CTIMPs

The Medicines for Human Use (Clinical Trials) Regulations set out the requirements for the management and storage of IMPs within a trial. All IMPs within the Trust must be managed by the Pharmacy Department in accordance with the Pharmacy Standard Operating Procedures. This management includes correct storage, temperature, monitoring, labelling and accountability of IMP in addition to compliance with any trial-specific procedures. Where it is not practicable to store the IMP in pharmacy and instead it must be stored in the clinical area, the Pharmacy Department will perform a risk assessment of the clinical area in accordance with the appropriate Pharmacy Standard Operating Procedure.

The labelling of IMP must be in accordance with Annex 13 of the EU Guidelines for Good Manufacturing Practice and all labels must be reviewed and approved by the Pharmacy Department prior to submission to the MHRA.

Safety Monitoring and Reporting for CTIMPs and ATIMPs

There are legal requirements for CTIMPs and ATIMPs regarding safety monitoring and reporting. Where the Trust acts as Research Sponsor, the responsibility for monitoring safety will be delegated to the main investigator at the site. For multiple sites this will be the responsibility of the CI to review safety data across all sites. This will involve review of all Serious Adverse Events (SAEs) through an established committee such as a Data Safety and Monitoring Committee (DSMC).

Safety reporting to the MHRA is also a legal requirement which allows the authority to identify when trial participants are at increased risk and where appropriate to assess when a trial should be modified or stopped. CIs, PIs and Research Sponsors have responsibilities for the recording and reporting of adverse events or reactions. Those events that are classified as Suspected, Unexpected, Serious Adverse Reactions (SUSARs) have particularly strict requirements with expedited reporting required within 7 days for fatal and life-threatening SUSARs or 15 days for non-fatal or non-life threatening SUSARs. Appropriate arrangements for safety reporting must be clearly outlined in the study protocol. The following Trust SOPs should be followed:

- For Adverse Event recording: see SOP-JRO-07 ‘Adverse Event Reporting for CTIMPs’
- For SUSAR reporting: see SOP-JRO-03 ‘Sponsor Process for reporting SUSARs’

The Trust will not issue Trust NHS Management Permission for a CTIMP or ATIMP without evidence of a favourable opinion for the study from an
NHS REC and a Clinical Trial Authorisation from the MHRA. During risk assessment of CTIMPS, the Trust will consider issues regarding the long term management of patients at the end of the trial in terms of appropriate exit strategies relevant to each study. The Trust will also require confirmation that monitoring arrangements are in place for CTIMPs and ATIMPS (see section below on Auditing and Monitoring) and confirmation of arrangements for safety reporting before Trust NHS Management Permission will be granted.

6.2.6. Good Clinical Practice Training

As it is an offence not to comply with the law for CTIMPs and ATIMPS, it is essential that they are regularly monitored to ensure compliance with the Medicine for Human Use (Clinical Trials) Act 2004 and the Amendment Regulations 2006 relating to GCP (see below for monitoring requirements).

To ensure that CTIMPs and ATIMPs are carried out in accordance with the principles of GCP, all staff involved in these studies must receive GCP training on a regular basis. For Clinical Trials taking place in the Trust staff must have completed a GCP training course with a recognised training body which explicitly includes full training on the EU Directives and the Statutory Instruments in the UK as described above. It is not sufficient to undertake project specific GCP training as a site initiation or an investigator’s meeting with a commercial company. The Trust requires that GCP training is updated every three years. Ad hoc training in between scheduled training events may be required, for example in the event that there are significant regulatory updates.

Investigators taking part in any research in the Trust are also required to have GCP training. For non-CTIMPs training must be undertaken within three months of receiving NHS Management Permission. If within the three months, confirmation of GCP training has not been provided to the Trust R&D Department, Trust NHS Management Permission will be withdrawn.


When proposed training is not a recognised GCP training course it will be assessed within the context of the research. Written confirmation of its suitability will be required from R&D before commencing the research.
GCP training sessions are provided by the Local Clinical Research Networks (LCRN) in accordance with National Institute for Health Research (NIHR) guidelines. These courses are available to all staff working on NIHR Portfolio research, as the principles of GCP apply to all research. Please see the LCRN’s website for more details: http://www.crncc.nihr.ac.uk/about_us/ccrn/ntw/news/training_form

There are also recognised on-line courses available as follows:

Provided by the NIHR
http://www.crncc.nihr.ac.uk/NR/exeres/B0309322-4852-4F52-ADB8-034B68194198

Provided by Infonetica Research Solutions (this training incurs a fee).
http://www.gcptraining.org.uk

Provided by The Institute of Clinical Research (this training incurs a fee).
http://www.icr-global.org/elearning/

6.2.7. Using Human Tissue in Research

Care is also needed when research involves tissue or organs. The Human Tissue Act 2004 (the Act) states that tissue classified as ‘relevant material’ under the Act that is to be stored for future, yet unspecified, research purposes must be stored in a facility which holds a research sector Human Tissue Authority licence.

To use donated tissue, researchers must obtain NHS REC approval and ensure that appropriate consent is in place for the intended use (unless a consent exemption exists, as specified in the Act).

Compliance with the regulations is overseen by an independent government watchdog, The Human Tissue Authority (HTA) which grants licences, conducts audits of licensed establishments, and provides guidance on the storage and use of human tissue and organs – http://www.hta.gov.uk

In addition, to support compliance, the HTA has issued a number of Codes of Practice to provide guidance and lay down expected standards for each of the sectors they regulate.

- For a list of relevant material under the Act, see: http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/definitionofrelevantmaterial.cfm
- For access to the HTA Codes of Practice, refer to: http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm
The Trust and Newcastle university each hold research sector HTA licences. For details on each institution’s arrangement for the storage, transfer and tracking on human tissue samples in accordance with the Act see the tissue section of the NJRO website – http://www.newcastlejro.org.uk/research-governance/research-involving-human-tissue-3/

6.2.8. Use of Patient Data

Data and information collected in the course of research must be recorded, handled and stored in a way that allows its accurate reporting, interpretation and verification to ensure data integrity. Furthermore, the appropriate use and protection of patient data should be paramount and particular attention must be given to systems for ensuring confidentiality of personal information.

The handling of personal information in research must be compliant with Trust policies in relation to the Data Protection Act 1998 and any data/confidentiality breaches must be reported using the Trust policy. To ensure the security of systems used in research for data collection, storage and transfer of data, all uses of patient data for research purposes must be reviewed by the Trust Caldicott Guardian (see SOP-JRO-09-001 ‘Obtaining Caldicott Approval for Research’)

All use of patient data for research purposes requires the consent of the patient. There are some exceptions where patient data can be used without consent under Section 60 of the Health and Social Care Act 2001. Requests for this use are made through the HRA Confidentiality Advisory Group (CAG) – http://www.hra.nhs.uk/resources/confidentiality-advisory-group

Evidence of Caldicott approval must be provided before Trust NHS Management Permission is granted. If data is to be used for research without consent then evidence of approval from CAG must also be provided to Trust R&D before NHS Management Permission will be granted.

6.2.9. Health, Safety and Employment/Honorary Status

The safety of research participants and research staff must be given priority at all times. Health and Safety Regulations and Trust policies or employing organisation’s Health and Safety policies must be strictly observed during the course of the research. This is particularly important if the research involves the use of potentially dangerous or harmful equipment, substances or organisms.
Appropriate employment arrangements must also be in place for research staff. For NHS staff, evidence of their employment status will be required. Researchers not employed by any NHS organisation who interact with research participants in a way that has a direct bearing on the quality of their care should hold an NHS Honorary Research Contract.

Other arrangements will be made for non-NHS staff where their research does not have a bearing on the quality of patient care (see SOP-JRO-10 ‘Access requests for Research under the Research Pass Scheme’). It is the responsibility of the CI or PI at each site, to ensure staff have the necessary contracts or letters of access in place before beginning research work within the Trust.

6.2.10. Intellectual Property (IP)

It is a requirement of the RGF that consideration is given to the exploitation of IP rights. Arrangements should be in place about ownership, exploitation and income from any IP that may arise from research.

IP is considered in every commercial project as part of the Trust NHS Management Permission process through review of the research contracts.

6.2.11. Monitoring and Audit

Organisations and individuals involved in research are expected to be able to demonstrate compliance with the RGF and the requirements in legislation and regulations described within the Framework. Systems are required that should include a risk-based programme of routine and random monitoring and audit.

It is also a statutory requirement that CTIMPs (including ATIMPs) are conducted in accordance with the principles of GCP. Working to GCP principles involves meeting stringent criteria in respect of study documentation, safety monitoring and reporting, data capture and management, study monitoring, training of study personnel and study conduct in general. Meeting these standards has significant resource implications in terms of time, personnel, equipment, software etc. It is imperative that investigators plan and budget for meeting these obligations of regular monitoring.

If a study has a commercial sponsor, then it would be expected that the commercial company (or a delegated Contract Research Organisation) would conduct and monitor the study in accordance with GCP guidelines.
If the Trust acts as Research Sponsor for a CTIMP/ATIMP then it is the CI’s responsibility to organise monitoring. This will normally be provided through a registered Clinical Trials Unit (CTU). For a list of UKCRN accredited CTUs see: http://www.ukcrn.org.uk/index/clinical/registered_ctus.html

Evidence of this will be required prior to NHS Management Permission including clear, documented delegation of Sponsor responsibilities. In exceptional circumstances, where a registered CTU does not provide this function, a clear documented plan of how responsibilities will be met along with written approval from the Sponsor will be required.

In accordance with JRO-SOP-16 ‘Auditing of Research Studies’, the Trust conducts yearly audits of approved research projects in line with the requirements of the RGF and core standards. This SOP states that a percentage of randomly selected projects will be audited each year along with other directed audits, as necessary, at the request of the Associate Medical Director for R&D and the Clinical Director of R&D.

6.2.12. Study Agreements/Contracts

Before a piece of research can start sponsors and host institutions need to have appropriate agreements in place which set out the responsibilities of the parties involved in the research. Considerable time and effort can be required to draft different versions of such agreements for the various research scenarios. The UK Clinical Research Collaboration (UKCRC) and stakeholders have developed a suite of model agreements which can be used “off the shelf” without modification – http://www.ukcrc.org/regulationgovernance/modelagreements

Commercial Studies

For commercial CTIMPs the Trust expects that commercial companies will use the national model Clinical Trial Agreement template (mCTA or CRO mCTA) for pharmaceutical companies working with the NHS.

For commercial studies involving medical devices, the Trust expects that commercial companies will use the national model Devices Clinical Investigation Agreement template (devices mCIA).

Non-Commercial Studies

For non-commercial studies the Trust expects that other non-commercial partners will use the national non-commercial Clinical Trial Agreement template (mNCA).
For all hosted CTIMPs and ATIMPs the Trust will require a clinical trial agreement to be in place before Trust NHS Management Permission is granted.

A requirement of the Research Governance domain of the core standards is that NHS organisations have clear and documented agreements in place for complex studies. For complex studies that are not CTIMPs, the Trust will request a study agreement from the sponsor or if the Trust acts as sponsor, then the Trust will initiate study agreements for each participating site. This will be decided on a project by project basis for non-CTIMP studies.

6.2.13. Indemnity

The Trust provides standard NHS indemnity to compensate anyone harmed by negligence by its employees. The Trust does not provide compensation for non-negligent harm. NHS Indemnity may be extended to research partners, e.g. academic researchers, who are not directly employed by the NHS through honorary research contracts where appropriate (i.e. where the researcher has a direct bearing on the care of the Trust’s patients).

Full indemnity arrangements for joint research between the Trust and Newcastle University are outlined in the Partnership Agreement and Memorandum of Understanding.

For commercial CTIMP studies, commercial companies will be expected to provide cover for negligent and non-negligent harm under the standard Clinical Trial Compensation Guidelines recommended by the Association of the British Pharmaceutical Industry. This should be clearly outlined in the Clinical Trial Agreement.

6.2.14. Fraud and Misconduct or other Incidents in Research

The NHS Counter Fraud and Security Managements Services have overall responsibility for all work to counter fraud and corruption within the NHS. Controls assurance systems under Standards for Better Health require healthcare organisations to check whether there are mechanisms to detect and investigate possible fraud, and to take appropriate action.

The partnership agreement between the Trust and Newcastle University sets out joint arrangements for handling fraud or misconduct for joint research projects in accordance with the Trust’s policies and the University’s policies.
The Trust’s systems of monitoring and auditing also provide mechanisms for detecting any evidence of mismanagement, fraud or other scientific or professional misconduct. Suspected fraud or misconduct will be investigated using the Trust’s policies and disciplinary procedures.

The JRO-SOP-04 ‘Research Misconduct and Fraud’ outlines the procedures for investigations related to research to ensure risk is monitored and managed. This links with the Trust ‘Fraud Policy and Response Plan’ for crossover between research and clinical incidents.

6.2.15. Patient and Public Involvement (PPI) in Research

Wherever possible patients, service users and carers should be involved in the design, conduct, analysis and reporting of research. National organisations such as INVOLVE are working to support and promote active public involvement in the NHS and this includes involvement in research (see http://www.invo.org.uk/). The Trust expects investigators to consider PPI, as appropriate, to their research.

6.2.16. Dissemination of Results and Information

When established, findings (including negative findings) should be published in a way that allows critical review and dissemination through the accepted scientific and professional channels. Findings must be made accessible to those participating in research and to those who could benefit from them.

Other researchers should have access to the data on which the findings are based. The information should address different media and writing styles for different audiences and unless the research ethics committee agrees otherwise, those consenting to be involved in a study should have ready access to the findings at the end of the study.

6.2.17. End of Study Notification and Archiving

It is the responsibility of the investigator at the site to inform the Trust when a study has ended. The definition of end of trial or study must be included in the study protocol.

For CTIMPs and ATIMPs it is a statutory requirement (Article 10 (c) of Directive 200/20/EC) that the MHRA, as the Competent Authority, is notified of the end of the trial within 90 days or within 15 days if the Trial is terminated early or halted.

Once completed, study documentation must be archived appropriately. For CTIMPs and ATIMPs where the Trust acts as Research Sponsor,
documents must be archived at the Trust approved off-site archiving facility so that documents can be easily retrieved for audit or inspection by Regulatory Authorities. Please see WI-JRO-001 ‘Instructions for Archiving’.

7  Training

7.1. All research staff must have read and understood those JRO SOPs and Working Instructions that are applicable to their research study prior to commencing the study. This training must be documented in the form of a SOP reading log.

7.2. Training courses in research-related subjects are provided by the LCRN specifically courses in GCP and taking informed consent for research.

7.3. Information and guidance is provided by the R&D team and is also available through the NJRO website: www.newcastlejro.org.uk

8  Equality and Diversity

The Trust is committed to ensuring that, as far as is reasonably practicable, the way we provide services to the public and the way we treat our staff reflects their individual needs and does not discriminate against individuals or groups on any grounds. This document has been appropriately assessed.

9  Monitoring Compliance

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<td>R&amp;D Team</td>
<td>Joint Research Executive</td>
<td>Ad hoc</td>
<td></td>
</tr>
</tbody>
</table>

10  Consultation and Review

The processes and roles in this policy have been reviewed and agreed by the R&D Executive.

11  Implementation

Changes to Policy highlighted in Trust Policy Update newsletter
Changes to Policy highlighted in R&D newsletter
Changes communicated to Team Leads for distribution to research teams.
Information about the conduct and review of Clinical Research along with the processes for project review by the R&D Approvals Committee is available through the intranet and the Newcastle JRO website – www.newcastlejro.org.uk

12 References


13 Associated Documentation

This policy should be read in accordance with the following Trust policies, procedures and guidelines:

- Confidentiality and Security (Data Accreditation) Policy
- Fraud Policy and Response Plan
- Information Governance Policy
- Research Passport Scheme Policy
R&D APPROVALS COMMITTEE
Terms of Reference

CONSTITUTION – the following post holders
  Chair of the R&D Approvals Committee*
  Clinical Director of R&D
  Head, Joint Research Office
  Research Governance Manager
  Assistant Director of Finance
  Assistant Director of Pharmacy
  Newcastle Clinical Trials Unit representative
  NIHR Operations Manager and/or Research Matron
  Research Finance Officer
  [*NB the Chair must have a clinical background]

In Attendance
  Other members of the R&D Department in support of specific projects
  Others co-opted as required

QUORUM
  Either the Chair of the Committee or the Clinical Director of R&D must be present plus the
  Head, Joint Research Office, the Research Governance Manager or a Research Management
  and Governance Manager.

  Project-specific comments may be received in written form from members of the Committee
  where attendance is not feasible.

FREQUENCY OF MEETINGS
  The Committee will meet approximately every two weeks.

ACCOUNTABILITY
  The R&D Approvals Committee will report routinely to the R&D Executive and the Joint
  Research Executive through the Clinical Director of R&D and the Head, Joint Research Office,
  plus to other specific Trust bodies as required (e.g. the Clinical Governance and Policy
  Committee, etc.)

LIAISON WITH
  Joint Research Office
  R&D Executive
  Joint Research Executive (JRE)
  JRE Scientific Committee
PURPOSE

To review proposals to conduct research within The Newcastle upon Tyne Hospitals NHS Foundation Trust and to ensure that research is conducted in the best interests of research participants and in accordance with relevant legislative and Department of Health requirements. The Committee will consider general issues relating to the research conducted in the Trust.

TERMS OF REFERENCE

- Research Project applications will be received and reviewed for approval – applications will be either approved, approved subject to specific issues being addressed, or not approved.

- Research projects assessed as low risk and with no irresolvable issues identified following the risk assessment may be approved by the RGM or RM&G manager prior to the meeting. They will be added to the agenda for Committee information only.

- The Clinical Director of R&D and the Head, Joint Research Office (or their deputies) will jointly agree the approval status of each project application following discussion by the Committee.

- Should the Clinical Director of R&D and the Head, Joint Research Office be unable to agree on the approval status of a project, determining the status will be deferred until further discussion has taken place with the Medical Director.

- Applicants will be notified of the Committee’s decision within two weeks of the meeting and, if an application has not been approved, the reasons for this decision will be provided to the applicant.

Investigators may appeal in writing within 60 days of any Committee decision to the Clinical Director of R&D indicating the basis as to why they consider the decision of the Committee is incorrect. The Clinical Director of R&D will review the application and respond within 45 days, indicating if any change to the approval status has been made. Should an Investigator consider the reviewed decision of the Clinical Director of R&D as being inconsistent with regulatory and legal requirements or unreasonable in relation to the information provided, an appeal may be made in writing to the Medical Director, indicating the basis on which the decision of the Committee is deemed to be incorrect. If the Medical Director considers there are reasonable grounds for appeal, the application will be considered by a panel comprising the Medical Director, Chair of the JRE and the Chair of the JRE Scientific Committee.
Appendix 2

Sponsorship Guidelines

The Trust will act as sponsor for:
- Projects involving Trust patients, their tissue, organs or data.
- Projects involving Trust staff as research participants.
- Research taking place on Trust premises or using Trust services or facilities
- Invasive projects with no Trust involvement where the Chief Investigator is a substantive employee of the University and holds an honorary research or honorary clinical contract with the Trust.

The University will act as sponsor for:
- Non-invasive research involving participants recruited outside of the NHS and this research is carried out by University staff.
- Projects involving tissue from a licensed tissue bank where the license is held by the University and all analysis will be carried out on University premises.

Other Projects:
As stated above, the University will only sponsor those studies that have very limited NHS involvement and where the research is non-invasive, specifically carrying no clinical risk. Those projects that are instigated by a University investigator without an honorary clinical contract with the Trust and fall outwith of these requirements may be sponsored by the Trust but each of these projects will be assessed and classified individually by Trust R&D using the criteria listed below.

1. Low risk projects:
Those projects that are classified as low risk will be sponsored by the Trust however investigators of these projects will be expected to:

- Ensure appropriate insurance/ indemnity arrangements are in place
- Sign a declaration form to confirm that they will comply with all of the conditions and responsibilities assigned to them by the Trust
- Conduct the research in accordance with the appropriate NJRO SOPs
- Allow the project to undergo audit by the Trust if randomly chosen to do so as part of the annual audit cycle

2. Medium risk projects:
Those projects that are classified as medium risk may be sponsored by the Trust however each project will need to undergo a formal review prior to this being agreed. In addition to complying with the above requirements, investigators will also:

- Allow the project to undergo mandatory audit by the Trust in line with the NJRO Audit SOP.

3. High risk projects:
Those projects that are classified as high risk may be sponsored under exceptional circumstances. Investigators will need to meet all requirements imposed by the Trust e.g. for CTIMPs and ATMPs the trial must be managed and monitored by a UKCRC registered Clinical Trials Unit. These projects will be reviewed by a committee composed of the Trust’s Research Governance Manager, the Clinical Director of R&D and the Associate Director of Pharmacy. Other members may be co-opted in depending upon the complexities of the trial.
<table>
<thead>
<tr>
<th>Project type</th>
<th>Low</th>
<th>Medium</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>Projects administering questionnaires/interviews for quantitative analysis or using mixed quantitative/qualitative methods</td>
<td>X</td>
<td></td>
<td></td>
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<tr>
<td>Projects involving qualitative methods only</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Projects limited to the use of human tissue samples and data</td>
<td></td>
<td>X</td>
<td></td>
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<tr>
<td>Projects limited to working with data</td>
<td></td>
<td>X</td>
<td></td>
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<tr>
<td>Basic science projects involving procedures with human participants e.g. MRI scans, physical tests</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Projects taking new tissue samples</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Trial of an intervention used in routine clinical practice or with a slight deviation from current practice e.g. surgical trials</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Trial of a CE marked medical device</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Clinical Trials of Investigational Medicinal Products (CTIMP)</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Trials of Advanced Therapy Medicinal Products (ATMP)</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Trial of a non-CE marked medical device</td>
<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>
This form must be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

<table>
<thead>
<tr>
<th>Policy Title:</th>
<th>Research &amp; Development Policy</th>
<th>Policy Author:</th>
<th>Ms Susan Ridge, Research Governance Manager</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Yes/No?</td>
<td>You must provide evidence to support your response:</td>
</tr>
<tr>
<td>1.</td>
<td>Does the policy/guidance affect one group less or more favourably than another on the basis of the following: (* denotes protected characteristics under the Equality Act 2010)</td>
<td>Policy applies does not affect any group more or less favourably than another and is underpinned by the Trust’s overriding policy on Equal Opportunities.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Race *</td>
<td>no</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ethnic origins (including gypsies and travellers)</td>
<td>no</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Nationality</td>
<td>no</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Gender *</td>
<td>no</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Culture</td>
<td>no</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Religion or belief *</td>
<td>no</td>
<td></td>
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<tr>
<td></td>
<td>Sexual orientation including lesbian, gay and bisexual people *</td>
<td>no</td>
<td></td>
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<tr>
<td></td>
<td>Age *</td>
<td>no</td>
<td></td>
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<tr>
<td></td>
<td>Disability – learning difficulties, physical disability, sensory impairment and mental health problems *</td>
<td>no</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Gender reassignment *</td>
<td>no</td>
<td></td>
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<tr>
<td></td>
<td>Marriage and civil partnership *</td>
<td>no</td>
<td></td>
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<tr>
<td></td>
<td>Pregnancy and maternity *</td>
<td>no</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Is there any evidence that some groups are affected differently?</td>
<td>no</td>
<td>There is no evidence to support any group is affected differently</td>
</tr>
<tr>
<td>3.</td>
<td>If you have identified potential discrimination which can include associative discrimination i.e. direct discrimination against someone because they associate with another person who possesses a protected characteristic, are any exceptions valid, legal and/or justifiable?</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>4(a).</td>
<td>Is the impact of the policy/guidance likely to be negative? (If &quot;yes&quot;, please answer sections 4(b) to 4(d)).</td>
<td>no</td>
<td></td>
</tr>
<tr>
<td>4(b).</td>
<td>If so can the impact be avoided?</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>4(c).</td>
<td>What alternatives are there to achieving the policy/guidance without the impact?</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>4(d).</td>
<td>Can we reduce the impact by taking different action?</td>
<td>n/a</td>
<td></td>
</tr>
</tbody>
</table>

Comments: Action Plan due (or Not Applicable): N/A

Name and Designation of Person responsible for completion of this form: Ms Susan Ridge
Date: 27th Feb 2014

Names & Designations of those involved in the impact assessment screening process: Ms Susan Ridge, Research Governance Manager R&D, Ms Jill Peacock, RM&G Manager R&D

(If any reader of this procedural document identifies a potential discriminatory impact that has not been identified on this form, please refer to the Policy Author identified above, together with any suggestions for the actions required to avoid/reduce this impact.)

For advice on answering the above questions please contact Frances Blackburn, Head of Nursing, Freeman, or, Karen Pearce, Senior HR Manager (Projects). On completion this form must be forwarded electronically to Steven Stoker, Clinical Effectiveness Manager, (Ext. 24963) steven.stoker@nuth.nhs.uk together with the procedural document. If you have identified a potential discriminatory impact of this procedural document, please ensure that you arrange for a full consultation, with relevant stakeholders, to complete a Full Impact Assessment (Form B) and to develop an Action Plan to avoid/reduce this impact; both Form B and the Action Plan should also be sent electronically to Steven Stoker within six weeks of the completion of this form.

October 2013