North, Central and South Manchester
Clinical Commissioning Groups

NHS

Policy Document

Clinical Audit and Research Governance Policy

Version: **1**

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Document Control Sheet

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Author(s) name:	David Smith, Corporate Governance Manager		
Department/Team:	Corporate Governance Team		
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This document is to be read in conjunction with the following documents: *Information Governance Policy* *Standards of Business Conduct & Conflict of Interest Policy*			

Version Control

Version	Date	Brief description of change
0.1	07.2014	First draft
0.2	09.2014	Second draft (clinical audit section expanded, request form added)
0.3	10.2014	Third draft (flowcharts, responsibilities, contacts list, EA added)

PLEASE NOTE: the formally approved copy of this document is held on North, Central and South Manchester CCG's website. Printed copies or electronic saved copies must be checked to ensure they match the current online version.

Contents

Appendices

1.0	Policy Statement
1.1	North, Central and South Manchester Clinical Commissioning Groups (hereafter referred to as 'the CCG' or 'the organisation') have a statutory responsibility to promote research. This policy outlines the protocol for pursuing or conducting clinical audit and research by members and employees of the CCG.
2.0	Introduction
2.1	The NHS Constitution outlines seven key principles that guide the NHS in all that it does. Part of this is a commitment "to innovation and to the promotion, conduct and use of research to improve the current and future health and care of the population".
2.2	Healthcare research is the basis of evidence-based practice. This is central to the care provided throughout the NHS and, as such, all commissioning decisions made by the CCG. Under the Health and Social Care Act 2012, the CCG has an obligation to promote research, in order to improve the quality of treatment and to advance public health. Commissioning and managing research is handled by the Local Clinical Research Network (CRN) for Greater Manchester, who provide this service for all CCGs in the Greater Manchester area. The CRN also have a co-ordinating role for all clinical research conducted and commissioned by local provider Trusts.
2.3	The CCG does not have a practical role in research governance; this service is currently provided by the CRN. Instead, the role of CCG personnel regarding clinical research is to engage with member practices and providers, and to encourage participation and contribution.
2.4	NHS bodies have a responsibility to "monitor, and make efforts to improve continuously, the quality of healthcare they commission or provide". Clinical audit is conducted to make sure healthcare providers meet agreed standards. It can be used to measure the CCG's performance in directly-funded healthcare, and to measure the performance of our providers.
3.0	Purpose
3.1	Should members or employees of the CCG wish to conduct or commission research, they are advised to contact the CRN as a matter of first recourse; this document will provide an overview of the concepts governing research in the NHS, and the steps required to gain permission to conduct it.
3.2	Due to the CCG's limited role in conducting research governance, this policy is designed to demonstrate that provision of governance is in place through the CRN, and to provide measures by which the suitability of the governance process can be assured.

3.3	The CCG and its providers hold patient data that may be involved in clinical audit, and appropriate handling of this data is discussed in this document.
4.0	Responsibilities
4.1	**CCG Board and Accountable Officer** The Accountable Officer is ultimately responsible for how the CCG's data is stored and accessed, and for the CCG meeting its statutory responsibility to promote research. As such, their role is to ensure that: • All staff take appropriate opportunities to promote clinical research; • The CCG as a whole helps facilitate best practice through audit and research by enabling it where possible; • All staff observe relevant information governance and confidentiality policies and responsibilities in doing so.
4.2	**Committees** The Committee responsible for Clinical Quality issues in each CCG will be responsible for appropriate monitoring of research and clinical audit being conducted in concert with the CCG, for approving clinical audit proposals, and for ensuring effective implementation of this policy.
4.3	**All staff** All CCG members and employees who handle patient data or who might have an involvement in clinical research or audit should note this policy, and ensure they take appropriate opportunities to facilitate research while observing CCG and provider policies on information governance and security. Any audit or research project that requires access to patient data held by the CCG should be assessed and approved by the Information Governance team. It is the responsibility of anyone either requesting or granting access to such data to ensure that this happens before any patient data is accessed.
5.0	Definitions of Terms Used
5.1	**Research** – Clinical research is used to determine the effectiveness of current or proposed interventions. This will usually involve trialling medication, diagnostic equipment, surgery, or programmes of care against existing best practice. Research arrangements are usually handled by locally or nationally-commissioned providers and responsibility lies with those conducting the study. Persons wishing to conduct research involving patients directly accessing services from the CCG are advised to contact the Greater Manchester Clinical Research Network as a first step. **Clinical Audit** – Defined by NICE as "a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change". Where

research examines effectiveness of treatment against a control, audit examines adherence to best practice and views outcomes through that lens. Clinical audit will not require ethics approval and can be conducted using CCG records or at Trusts. If you require access to data for clinical audit, contact the organisation holding it who will have their own policies, procedures and authorisation process. Within the CCG, direct the request to the Quality and Information Governance teams.

CRN – The Greater Manchester Clinical Research Network are responsible for governance and management of research conducted in primary care, and help co-ordinate research conducted in secondary care. CCG staff looking to conduct or participate in clinical research should make contact with the CRN to plot their next steps.

NIHR – The National Institute for Health Research is a Department of Health-funded organisation which oversees and supports research conducted within the NHS. Research bodies and services such as the CRN, CLAHRCs and the Clinical Trials Gateway operate within the NIHR, who may also offer assistance with ETC funding in exceptional circumstances.

Quality Committee – Each CCG has a quality committee, which meets monthly or bi-monthly to discuss matters relating to clinical governance and care standards. Research falls within their purview as the aim of clinical research in the NHS is to provide the best possible treatment; on a local level, the Quality Committee may wish to prioritise resource allocation (including funding and staff time) towards certain areas of care.

Governance Committee – Each CCG has a governance committee, which is responsible for overseeing issues relating to corporate and information governance for the group and its employees. They will be responsible for considering risks to confidentiality involved in access to CCG-held patient data, and for gaining assurance about research or audit programmes that do so.

Information Governance – Procedures relating to the handling of patient data form part of information governance. Requests to view data held by the CCG will be considered by the Information Governance team; persons conducting research or clinical audit should always be careful to abide by Caldicott principles and make sure patient data is stored securely and is not handled except where necessary and approved.

Consent – Patients participating in clinical research should always know that they are taking part and should provide agreement before receiving non-standard treatment. Patients whose data is part of clinical audit are considered to have given consent if they have been made aware that their data may be used for this purpose and have not objected; if they have objected, or if they have had access to this information, their data should not be used in clinical audit.

Excess Treatment Costs – Where a piece of clinical research involves

	patients receiving a different intervention to that normally offered by the healthcare provider conducting the research, additional costs (relating to additional staff time, extended hospital stays, additional medication outside that subject to a clinical trial etc) may be incurred. The cost of continuing to provide the trialled intervention to all patients who would be offered it for the duration of their treatment is referred to as the Excess Treatment Cost (ETC). It is considered to be the responsibility of the NHS (rather than the researcher) to provide this as routine care, and an agreement to fund it must be in place before clinical research begins. ETCs can involve a cost saving as well as increased expense; for instance, where a new surgical technique leads to shorter recovery periods and quicker discharges. **Anonymised data** - Anonymised data contains no information that the recipient could use to identify the patient(s) involved. **Pseudonymised data** - Pseudonymised data is anonymous to the recipients, but contains information that would allow others (such as healthcare staff responsible for the patient) to identify the patient(s) involved. **Weakly pseudonymised data** contains a single element of identifiable data (such as an NHS number or date of birth) that could lead to identification of the patient, and should only be held within sites that have achieved Accredited Safe Haven status (such as the CCG). **Personal Confidential Data (PCD)** - Personal Confidential Data contains information which could be used to identify the patient(s) involved. This includes singular pieces of identifiable information such as a name, address, or NHS number, as well as identifying packages of information, such as date of birth along with postcode area. **Non-Clinical Research/Audit** – There will be times when CCG members, employees or external bodies will want to look at CCG business or personnel. Examples include staff surveys, or academic interest in NHS finances. As these cases do not require access to patient data, it is the responsibility of Senior Management to decide what to approve (with due consideration of Information Governance issues).
6.0	The CCG's Responsibilities for Research
6.1	According to the Health and Social Care Act (2012), the CCG has a responsibility to promote research. The CCG primarily discharges this responsibility by providing information to GPs and patients about research being conducted in primary care, so that patients can participate in research for which they are eligible and our practices are aware of new studies they may wish to be involved in.
6.2	Information about research studies taking place is received by the CCG from a variety of sources – the Clinical Research Network, local universities, and other research networks and organisations active locally and nationally. The CCG will publish information about all research it is made aware of; firstly, by

	including opportunities for patients to participate in the Talking Health e-bulletin and for GPs in the local newsletters, and secondly, by publishing both the opportunities and the newsletters on the CCG's website.
7.0	Acquiring Research Approval
7.1	The Clinical Research Network for Greater Manchester is the first port of call for any questions or requests relating to clinical or healthcare research; contact details can be found in Appendix E. All clinical research must have a suite of approvals as relevant to the scope of the study; the National Institute for Health Research (NIHR) provides the Co-ordinated System for gaining NHS Permission (CSP), by which researchers and project leads can pursue approval and permission from all ethical and regulatory bodies relevant to the research being conducted. These bodies will commonly include the Medicines and Healthcare Regulatory Agency (MHRA), the Confidentiality Advisory Group (CAG), and a Research Ethics Committee (REC) provided by the DH's Research Ethics Service; other committees in specialist fields may also be contacted. Advice may also be sought from the Health Research Authority (HRA), which is responsible for investigating and preventing misconduct by healthcare researchers.
7.2	**Defining Research** Audit, service evaluation and public health monitoring are not subject to the same rules and requirements as research. These kinds of work are routinely carried out, under the purview of a number of committees, and by nature should require minimal ethical approval. However, work of this ilk may require consideration as regards confidentiality, and discussion with your Caldicott guardian may be required. For further information, please see Appendix A.
7.3	**Pursuing research via the CRN** The CRN provide facilitation for healthcare professionals pursuing research. They will assist with the approvals process – signposting and helping prepare submissions to relevant ethics committees – and will provide assistance from a research governance perspective. This will entail making sure: that research activities are conducted within a framework preventing misspending or misallocation of resources, that participants are protected and are granting consent, that confidentiality and information security are observed, that reporting takes place appropriately, and that agreements with ethics committees or funding providers are adhered to.
8.0	Research Funding
8.1	Please be aware that there are strict rules and requirements around accepting funding or sponsorship for research projects. These are largely

	handled by the CRN and the CSP approval process, but please also consult the CCG's *Standards of Business Conduct and Conflicts of Interest Policy*.
8.2	The NHS is responsible for providing care to patients participating in clinical research. Where their participation may incur additional expenditure, an agreement must be sought to fund this additional care; expenditures of this sort are referred to as Excess Treatment Costs (ETCs). For primary care research, this funding will usually come from the primary care provider's budget or from funds available to the study itself. For secondary care research, ETCs are usually the sole responsibility of providers. Secondary care ETCs can potentially amount to substantial expense, and for this reason agreement to conduct research can be harder to reach.
8.3	Please note that the CCG is unlikely to be able to provide financial assistance with research, including ETCs; if you are looking to obtain this funding, you may be best advised to contact the CRN or speak directly to the relevant providers.
8.4	If you would like the CCG to consider a research grant application, or to provide funding for ETCs, please complete the Information form in Appendix C. Send your request along with this information to the Corporate Governance team; it will then be directed to the appropriate personnel and committees for consideration as laid out in Appendix F. Contact details are available in Appendix G.
9.0	Clinical Audit
9.1	NICE define clinical audit as "a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change." It differs from service evaluation programmes in that the quality of interventions and outcomes are measured against specific criteria, rather than care being investigated holistically (and, potentially, having measurement criteria identified in the process). It differs from research in that it does not require randomisation of participants, does not involve changing the care given before assessment begins, and will usually involve analysis of data that is gathered (routinely or otherwise) prior to the audit being conducted.
9.2	Clinical audit usually entails access to patient data that has already been collected. As a CCG, we may find that those patient records we hold are requested for audit, or that our members or staff wish to conduct or participate in an audit of data held elsewhere.

9.3	**Audit of Provider Data** If you are looking to audit data held by our providers or GP members, you will have to contact them directly; it will be their decision whether to grant access to this data and this may require you to submit a proposal. Most large providers will have proformas for this purpose, or will have clinical audit teams who will serve as a point of contact. In any case, anyone accessing data held by these organisations will be bound by the confidentiality agreements and policies they have in place. If members or employees of the CCG wish to audit data held by GPs or provider Trusts, they should request anonymised or pseudonymised data if at all possible. If there is a requirement to access PCD, this should be handled under the auspices of the GP or provider. The GP or provider is responsible for such an audit being conducted, and is responsible for ensuring local information governance policy is met. A member or employee of the CCG may wish to volunteer their services to personally conduct the audit, but this is subject to authorisation by the GP or provider. Access to PCD cannot be demanded by members or employees of the CCG owing to their role as a commissioner. Where access is granted it should only be used to fulfil a stated clinical objective and not for wider commissioning purposes. If data is being taken offsite, physically or electronically, it must first be aggregated, anonymised or pseudonymised as far as possible. PCD should not be taken offsite or duplicated for audit purposes under any circumstances.
9.4	**Audit of CCG Data** If you are looking to conduct an audit of patient data held by the CCG, please use the patient data access request form in Appendix B.
9.5	**Clinical Audit and Consent** Express consent is not required to view patient data for audit, provided that patients have been told (or have had easy access to material informing them) that their records may be accessed for these purposes by someone subject to a duty of confidentiality, and that they have not specifically objected to this happening. If a patient has refused consent or has not had sufficient opportunity to do so, their data may not be used for audit purposes.
10.0	Non-Clinical Research and Audit
10.1	Research and audit can be conducted involving the CCG or its staff in areas that do not touch on patient care, and which would not involve access to or consideration of patient data in any capacity. These studies can come both from within and without the CCG. As a public body, the CCG should not be resistant to work that could suggest

	improvements to the service provided, and these requests should be complied with unless doing so would threaten the CCG's ability to achieve its strategic objectives, either through resource demands (such as staff time) or by requiring publication of confidential or business-sensitive documents.
10.2	**Requests from external bodies** Where requests to conduct research or audit into the CCG or its staff come from academia or other public bodies, they should be evaluated by the Senior Management or Executive Team. The Information Governance team should be notified, and involved in managing access to CCG data if appropriate. External requests to access non-clinical data should use the access request form in Appendix B and tick 'Non-clinical/Business'.
10.3	**Requests from within the CCG** Where CCG members or staff wish to conduct research or audit of the organisation, this should be approved first and foremost by line managers. If this project could lead to external publication, or would require diversion of CCG resources, the request should be advanced to the Executive Team. (Information Governance should be involved.
11.0	Process for Approval & Ratification
11.1	Guidance has been sought from the Clinical Research Network prior to preparing this policy, and the input and assent of both the CRN and the Quality team at each CCG will be sought before producing a final draft.
11.2	The final draft of this policy will be presented to the Governance Committee of each CCG for approval.
12.0	Dissemination, Training & Advice
12.1	This policy will be published on the CCG website and a link will be distributed via Manchester Matters.
12.2	Appropriate managers will be notified of the existence and contents of the policy; any queries that arise will be supported as far as possible by the Corporate Governance Team.
13.0	Review, Monitoring and Compliance
13.1	This policy will be reviewed every three years, or whenever a significant change occurs in the way research is commissioned and managed by or on behalf of the CCG.
13.2	Research projects sponsored or funded by the CCG are the purview of the committee responsible for clinical quality issues. The committee will review the status of sponsored or funded research projects as a standing agenda

	item.
14.0	References
14.1	Legislation • *UK Parliament (2012)* ***Health and Social Care Act***
14.2	CCG Policies • *North, Central and South Manchester CCGs (2014)* ***Information Governance Policy*** • *North, Central and South Manchester CCGs (2013)* ***Standards of Business Conduct & Conflict of Interest Policy***
14.3	Guidance • *Department of Health (2005)* ***Research Governance Framework for Health and Social Care*** • *National Institute for Clinical Excellence (2002)* ***Principles for Best Practice in Clinical Audit*** • *Health Research Authority (2013)* ***Defining Research*** • *NHS Commissioning Board (2013)* ***The functions of clinical commissioning groups*** • *Department of Health (2013)* ***The NHS Constitution*** • *NHS England (2013-14)* ***Information Governance Bulletins***
14.4	Supporting Documentation • *Shropshire County PCT (2006)* ***Clinical Audit Policy*** • *Medical Research Council –* ***Data and Tissues Toolkit: Glossary*** [accessed 18 September 2014 at www.dt-toolkit.ac.uk/glossary.cfm]

Appendix A – Defining Research and Clinical Audit

(Adapted from http://www.hra.nhs.uk/documents/2013/09/defining-research.pdf)

<table>
<tr><th>Research</th><th>Service Evaluation</th><th>Clinical Audit</th></tr>
<tr><td>The attempt to derive generalisable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them.</td><td colspan="2">Designed and conducted solely to define or judge current care.</td><td>Designed and conducted to produce information to inform delivery of best care.</td></tr>
<tr><td>Quantitative research – designed to test a hypothesis.
Qualitative research – identifies/ explores themes following established methodology.</td><td colspan="2">Designed to answer: “What standard does this service achieve?”</td><td>Designed to answer: “Does this service reach a predetermined standard?”</td></tr>
<tr><td>Addresses clearly defined questions, aims and objectives.</td><td colspan="2">Measures current service without reference to a standard.</td><td>Measures against a standard.</td></tr>
<tr><td>Quantitative research – may involve evaluating or comparing interventions, particularly new ones.
Qualitative research – usually involves studying how interventions and relationships are experienced.</td><td colspan="3">Involves an intervention in use only. The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.</td></tr>
<tr><td>Usually involves collecting data that are additional to those for routine care but may include data collected routinely. May involve treatments, samples or investigations additional to routine care.</td><td colspan="2">Usually involves analysis of existing data but may include administration of interview or questionnaire.</td><td>Usually involves analysis of existing data but may include administration of simple interview or questionnaire.</td></tr>
<tr><td>Quantitative research – study design may involve allocating patients to intervention groups.
Qualitative research – uses a clearly defined sampling framework underpinned by conceptual or theoretical justifications.</td><td colspan="3">No allocation to intervention: the health professional and patient have chosen intervention before service evaluation/audit.</td></tr>
<tr><td>May involve randomisation.</td><td colspan="3">No randomisation.</td></tr>
<tr><td>Normally requires REC review. For more information: www.nres.nhs.uk/applications/approval-requirements</td><td colspan="3">Does not require REC review.</td></tr>
</table>

Appendix B – Clinical Audit: Request Form

Name of proposed audit:	
What is the goal of the audit?	
Which organisation or individual is conducting the audit?	
Are other sites involved in the study? Is the scope local, regional, national?	
Type of Data required:	□ Anonymised □ Pseudonymised □ PCD □ Non-clinical/Business
Dates access will be required:	Start Date: ...../...../..... End Date (projected): ...../...../.....
If PCD is needed: Why is pseudonymised data insufficient for the purposes of the audit?	
If PCD is needed: Only NHS employees in substantive posts may access PCD. Please provide the name and employer of any individuals who will access PCD as part of this audit:	
What CCG resources will be required to conduct this audit? (Desk space, secure storage, encrypted laptops etc)	

- Access to patient data is provided on the basis that it will only be used for agreed and approved purposes.
- PCD may only be accessed by a GP or senior clinician responsible for that patient's care, or by substantive NHS staff acting on their instruction.
- PCD must only be accessed with the consent of the patient in question. (Implied consent may be provided where the patient was informed that their data may be used for clinical audit, or had that information made easily available, and does not refuse permission. Make sure this is the case for all patients being audited.)
- PCD must not be taken offsite, whether it is in electronic or paper form or an original or duplicate copy.
- Persons handling PCD must obey national and local policies on Information Governance and Records Management; failure to do so may represent a criminal offence in some circumstances.

Please sign to say you understand and agree with the above conditions of access.

Signature..... Print Name..... Date.....

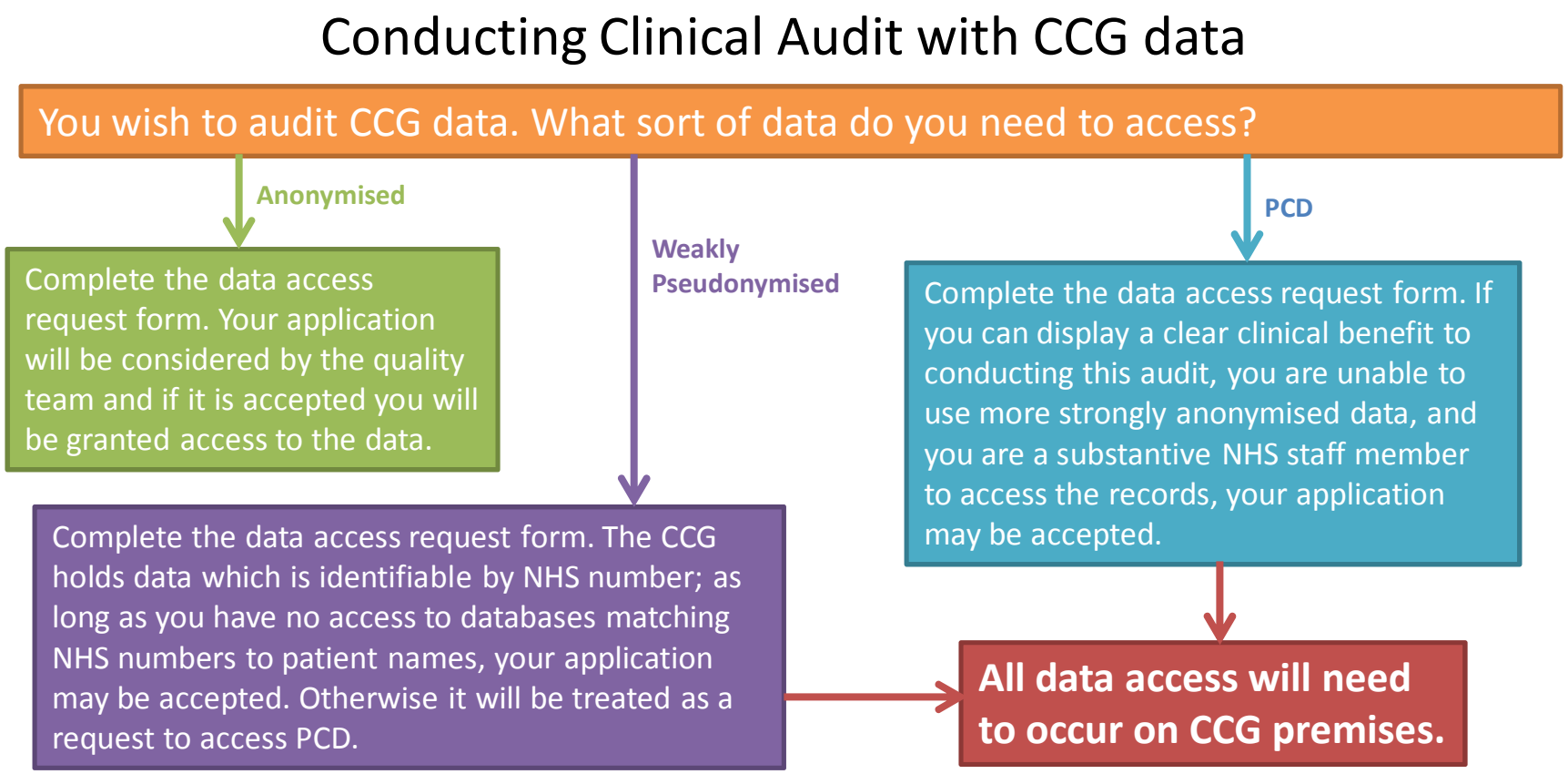
Appendix C – Research Funding Applications: Information Form

Please note that Research Management and Governance is provided to the CCG by the Greater Manchester Clinical Research Network; questions around - ethics approval, research passports, gaining consent etc - should be directed to the CRN (excepting where this involves care provided directly by the CCG). Please consult the Clinical Audit and Research Governance Policy for further details.

Please send completed forms to the CCG's Corporate Governance team. Date: .....

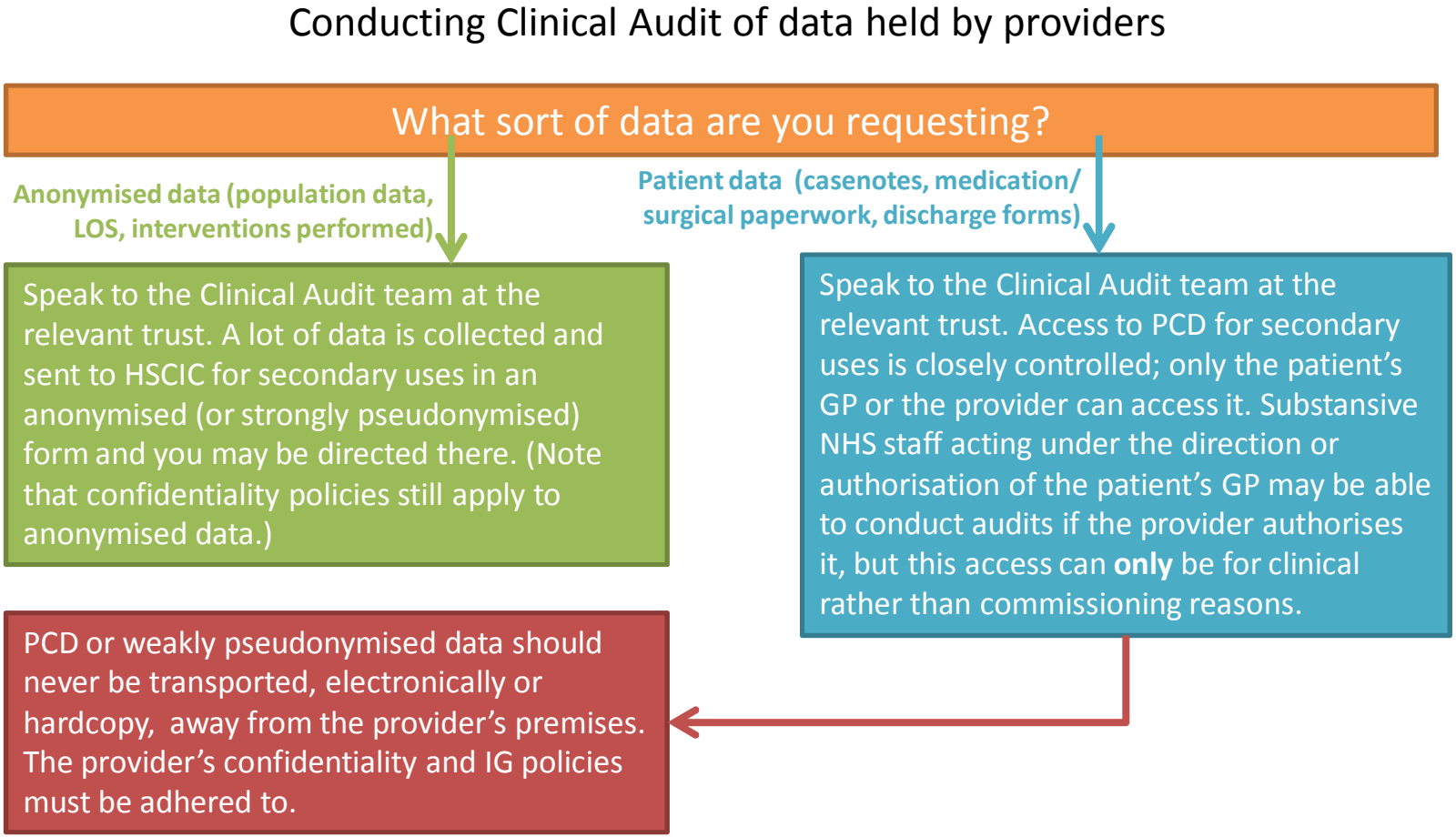
Name of study	
Aims of study	
Describe the study. *When and where will it be conducted? Is there a set patient group or fixed cohort size? What is the proposed intervention, and how does it differ from current practice?*	
What sort of funding are you looking for?	□ Full or partial funding for research costs □ Excess Treatment Costs □ Both
Where will/might these costs arise?	
What is the projected total cost to the CCG?	
Are you aware of any ongoing CCG projects or workstreams that this research will directly impact?	
Please provide key contact information:	**Name:** **Email:** **Name:** **Email:** **Name:** **Email:**

Appendix D – Clinical Audit: CCG Data Flowchart

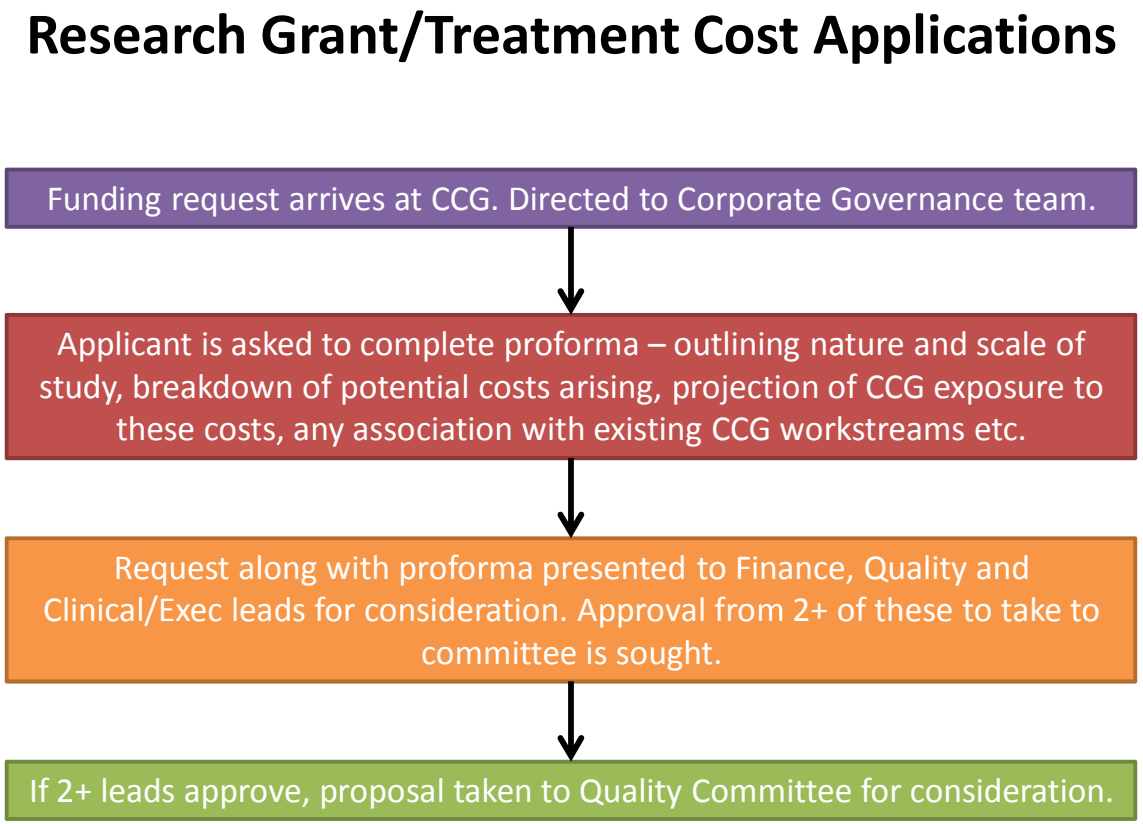


Data Access Request forms should be sent to **Corporate Governance.**

Appendix E – Clinical Audit: Provider Data Flowchart



Appendix F – Research Funding Applications: CCG Procedure Flowchart



Appendix G – Key Contacts List

External:

Greater Manchester Clinical Research Network
General Enquiries Tel: 0161 276 8005

Pennine Acute NHS Trust
Tel: 0161 624 0420

Central Manchester University Hospitals NHS Foundation Trust
Research and Innovation Division Tel No: 0161 276 3565

University Hospitals of South Manchester NHS Foundation Trust
Research and Development Team Tel: 0161 291 5890

Manchester Mental Health and Social Care NHS Trust
Research and Development Team Tel: 0161 276 3309

Internal:

Corporate Governance Team:
Corporate Governance Administrator:
Email: carrie.hale@nhs.net Tel: 0161 765 4249
Corporate Governance Manager:
Tel: 0161 765 4534

Information Governance Team: caroline.cross@nhs.net
Business Intelligence: graham.hayler@nhs.net
Quality and Performance: kate.provan@nhs.net

Appendix H – Equality Analysis

GMCSU Equality Analysis Form		
	The following questions will document the effect of your activity on equality, and demonstrate that you have paid due regard to the Public Sector Equality Duty. The Equality Analysis (EA) guidance should be used read before completing this form.	
	Section 1: Responsibility	
1	Name & role of person completing the EA:	David Smith, Corporate Governance Manager
2	Service/ Corporate Area	Corporate Services
3	Head of Service or Director (as appropriate):	Nick Gomm, Head of Corporate Services
4	Who is the EA for? Select from the drop down box.	North, Central and South Manchester CCGs
4.1	Name of Other organisation if appropriate	
	Section 2: Aims & Outcomes	
5	What is being proposed? Please give a brief description of the activity.	The policy governs the means by which clinical audit and research are conducted where it would involve the CCG, the records it holds, or its individual members or employees.
6	Why is it needed? Please give a brief description of the activity.	To provide guidance to staff.
7	What are the intended outcomes of the activity?	To enable CCG staff to conduct or participate in clinical audit and research.
8	Date of completion of analysis (and date of implementation if different). Please explain any difference	October 2014
9	Who does it affect? Select from the drop down box. If more than one group is affected, use the drop down box more than once.	CCG Staff
	Establishing Relevance to Equality & Human Rights	
10	**What is the relevance of the activity to the Public Sector Equality Duty? Select from the drop down box and provide a reason.**	

	General Public Sector Equality Duties	**Relevance (Yes/No)**	**Reason for Relevance**
	To eliminate unlawful discrimination, harassment and victimisation and other conduct prohibited by Equality Act 2010	Yes	Policy to be used by all staff
	To advance equality of opportunity between people who share a protected characteristic and those who do not.	Yes	Policy to be used by all staff
	To foster good relations between people who share a protected characteristic and those who do not	No	

10.1	**Use the drop down box and advise whether the activity has a positive or negative effect on any of the groups of people with protected equality characteristics and on Human Right**

	Protected Equality Characteristic	Positive (Yes/No)	Negative (Yes/No)	Explanation
	Age	No	No	
	Disability	No	No	
	Gender	No	No	
	Pregnancy or maternity	No	No	
	Race	No	No	
	Religion and belief	No	No	
	Sexual Orientation	No	No	
	Other vulnerable group	No	No	
	Marriage or Civil Partnership	No	No	
	Gender Reassignment	No	No	
	Human Rights	No	No	

If you have answered No to all the questions above and in question 10, explain below why you feel your activity has no relevance to Equality and Human Rights.

The policy covers the appropriate use of patient information for clinical audit and the means by which people conduct clinical research. While audit and research may lead to changing outcomes for patients, this policy has no influence on the outcome of research or audit being conducted.

Section 4: Equality Information and Engagement

11 What equality information or engagement with protected groups has been used or undertaken to inform the activity. Please provide details.

Details of Equality Information or Engagement with protected groups	Internet link if published & date last published
None	N/A

11.1	**Are there any information gaps, and if so how do you plan to address them**	None

Section 5: Outcomes of Equality Analysis

12 Complete the questions below to conclude the EA.

What will the likely overall effect of your activity be on equality?	Policy to be used by all staff.
What recommendations are in place to mitigate any negative effects identified in 10.1?	N/A
What opportunities have been identified for the activity to add value by advancing equality and/or foster good relations?	None
What steps are to be taken now in relation to the implementation of the activity?	Policy to be approved and made available to staff for guidance.

Section 6: Monitoring and Review

13 If it is intended to proceed with the activity, please detail what monitoring arrangements (if appropriate) will be in place to monitor ongoing effects? Also state when the activity will be reviewed.

The policy will be reviewed on a two-yearly basis barring any significant changes to national policy or guidelines or to the responsibilities of the CCG. No future impact on equality is anticipated to arise as a result of this policy.