

Research Governance Manual

North West London Section • Primary Care
Research Governance • Consortium



Brent **NHS**
Primary Care Trust

*Working with our partners
for a healthier Brent*

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Abbreviations List

ACPI	Accredited Primary Care Investigator
CEO	Chief Executive Officer
CI	Chief Investigator
COREC	Central Office of Research Ethics Committee
DH	Department of Health
LREC	Local Research Ethics Committee
MREC	Multi-centred Research Ethics Committee
PCT	Primary Care Trust
RGF	Research Governance Framework
RMGU	Research Management Governance Unit
RM&G	Research Management and Governance Unit
SHA	Strategic Health Authority
WeLReN	West London Research Network

Overview

1.1 Scope of this Manual

All organisations and individuals that wish to undertake research within primary care in the sector are expected to follow these agreements. Amendments are to be negotiated at the quarterly meeting of the North West London Primary Care Research Steering Group, to be attended by PCT Research Leads from all eight PCTs. These agreements flow from the Department of Health guidelines but are adapted to be relevant to the networked nature of primary care and the specific local context. This manual defines the roles and responsibilities of all in a way that facilitates both local innovation and collaborative reports.

It is intended to be a “live” document. At this stage the priority is to set up a clear and streamlined Research Management & Governance (RM&G) system that will facilitate high quality research – that is research that is feasible, useful, safe, legal, ethical and financially appropriate. This research will improve clinical processes and thus contribute to the development of high quality services throughout the sector.

In subsequent years the manual will evolve to outline more ambitious aims such as systems for morbidity surveillance, connecting research with both local and sector-wide development needs, and describing the whole sector as a case study of health service research. The present plans are being developed not only to address the immediate needs, but also to pave the way for these future aspirations.

Overview

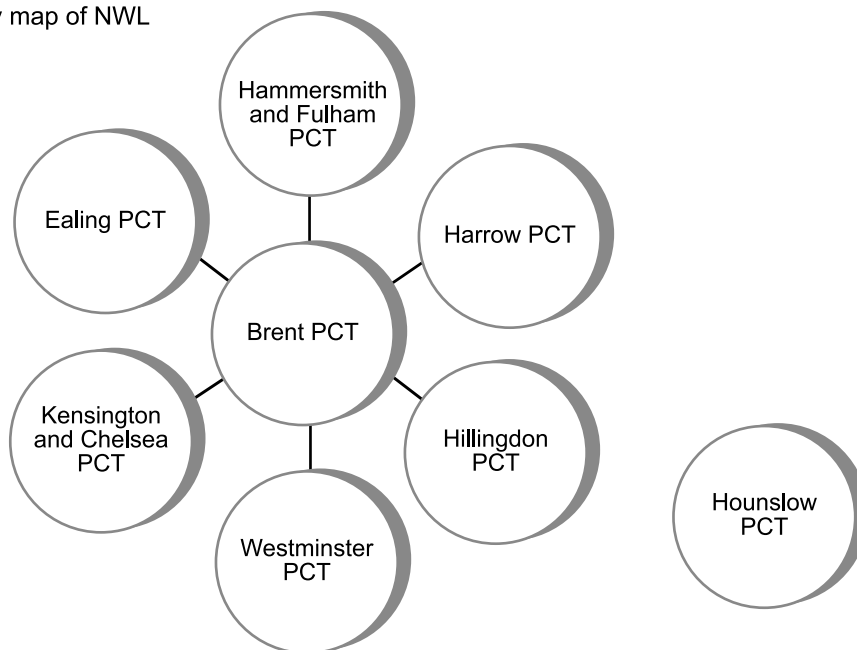
1.2 The North West London Health Care Sector

The Government introduced the concept of Research Governance as a quality assurance system for ensuring high standards of research practice across health and social care. The Department of Health Research Governance Framework for Health and Social Care defines a set of quality standards and requires reports to demonstrate that these standards are met.

All individuals and organisations involved in health and social care research have responsibilities within research governance. Primary Care Trusts have responsibilities as healthcare providers who use research, as employers of researchers, as builders of local research capacity, and in some cases as research sponsors.

Every Strategic Health Authority has a leading Primary Care Trust for research governance. In the North West London sector, Brent Teaching Primary Care Trust (PCT) takes the lead on organising research governance for seven (see below) of the Primary Care Trusts in the North West London sector. The eighth PCT wishes to be involved in all sector agreements, although it has a separate arrangement for research governance.

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Overview

1.3 Research Governance Domains

In accordance with “Research Governance Framework Document” all research activity within the NHS need to follow the protocols laid down in the framework. These are based on 5 domains:

Science

- Where appropriate, clear evidence of a literature search, a search of current research through the National Research Register.
- Not duplicating previous research.
- Appropriate sample sizes and methodology.
- A methodology that is clear, able to be implemented, and directed to finding the relevant results.
- Clear outcome objectives.

Ethics

- Written consent should always be obtained for any treatment provided for, or any sample or data taken from a patient that will form part of a research undertaking.
- The NHS has an absolute and binding duty of confidentiality to its patients and their data. This also applies fully to all honorary clinical contract holders. Therefore everyone (including Researchers or non-NHS staff) who accesses confidential data has the same duty of care towards this information. They must not disclose it to parties or bodies who have no right to it.
- Researchers must be careful in the collection and storage of their results and must anonymise them, wherever possible. If linkage to an individual is essential, extra care is called for to keep that information secure and restricted.

Consumer Involvement

- It is a requirement of the Research Governance Framework (RGF) that we involve consumers appropriately at all stages of research.

Finance

- All projects should be resourced properly.
- Financial probity and compliance with the law and with the rules laid down by H M. Treasury for the use of public funds are as important in research as in any other area.
- Indemnity should be provided to protect participants.
- Careful consideration must be given to the appropriate exploitation of intellectual property rights. It is important that results are not be disseminated publicly before they can be exploited. The NHS lives in a commercial world, and it has to utilise any intellectual property to maximum effect.

Overview

Health and Safety, Conduct and Organisation

- There should be free access to information both on the research being conducted and on the findings of the research, once these have been subjected to appropriate scientific review. This information must be presented in a format understandable to the public.
- Records must be kept in a secure fashion and not left in places where they can be accessed by unauthorised persons. Collected data must be stored in such a way that privacy of information is retained.
- Storage of the adverse event data will be useful in settling any future claims and in assessing the clinical risks associated with particular types of trial.
- All research on Trust sites has to be undertaken within the prevailing Health and Safety regulations.



Overview

1.4 Definitions

1.4.1 Research

Health Research is defined as any systematic activity that generates new knowledge that helps to understand health and illness, including the diagnosis and treatment of diseases and designing better ways of delivering healthcare.

1.4.2 Clinical Audit

Clinical Audit is the monitoring of clinical activity against established good practice guidelines, or developing guidelines from accepted research evidence. The activities of audit and research may be the same - it is the purpose to generate new knowledge of use in other places that distinguishes between research and audit. For example, guidelines development where there is little existing research evidence should be considered as innovation and research rather than audit.

Unlike research, audit does not usually require ethical committee approval and many of the guidelines in the manual do not apply. However it is the view of the Steering Group that both research and audit should be of high quality and result in learning. Leaders of audit may therefore find many of these agreements also of relevance to them.

1.4.3 Research Methods

These might involve:

- Quantitative methods such as experiments and questionnaires
- Qualitative methods such as interviews and focus groups
- Case studies, interventions and multiple methods approaches
- Historical research
- Participatory action research

1.4.4 Ethical consideration

Ethical consideration might be needed when:

- Asking for or using samples (tissues, fluids, whole organs)
- Undertaking additional diagnostic tests
- Requiring physical or psychological tests where full consent may be difficult
- Collecting data from patient records and Trust databases

The multifaceted nature of primary care makes it particularly appropriate for research to include multiple perspectives (e.g. multidisciplinary), multi-paradigm approaches (e.g. multiple methods) and local participation (e.g. within a learning community).

Overview

1.4.5 Innovation

Examples of innovation may include the introduction of new techniques that have been developed elsewhere, or development and initial small-scale piloting of new techniques prior to formal assessment.

1.4.6 Routine data collection including patient satisfaction surveys

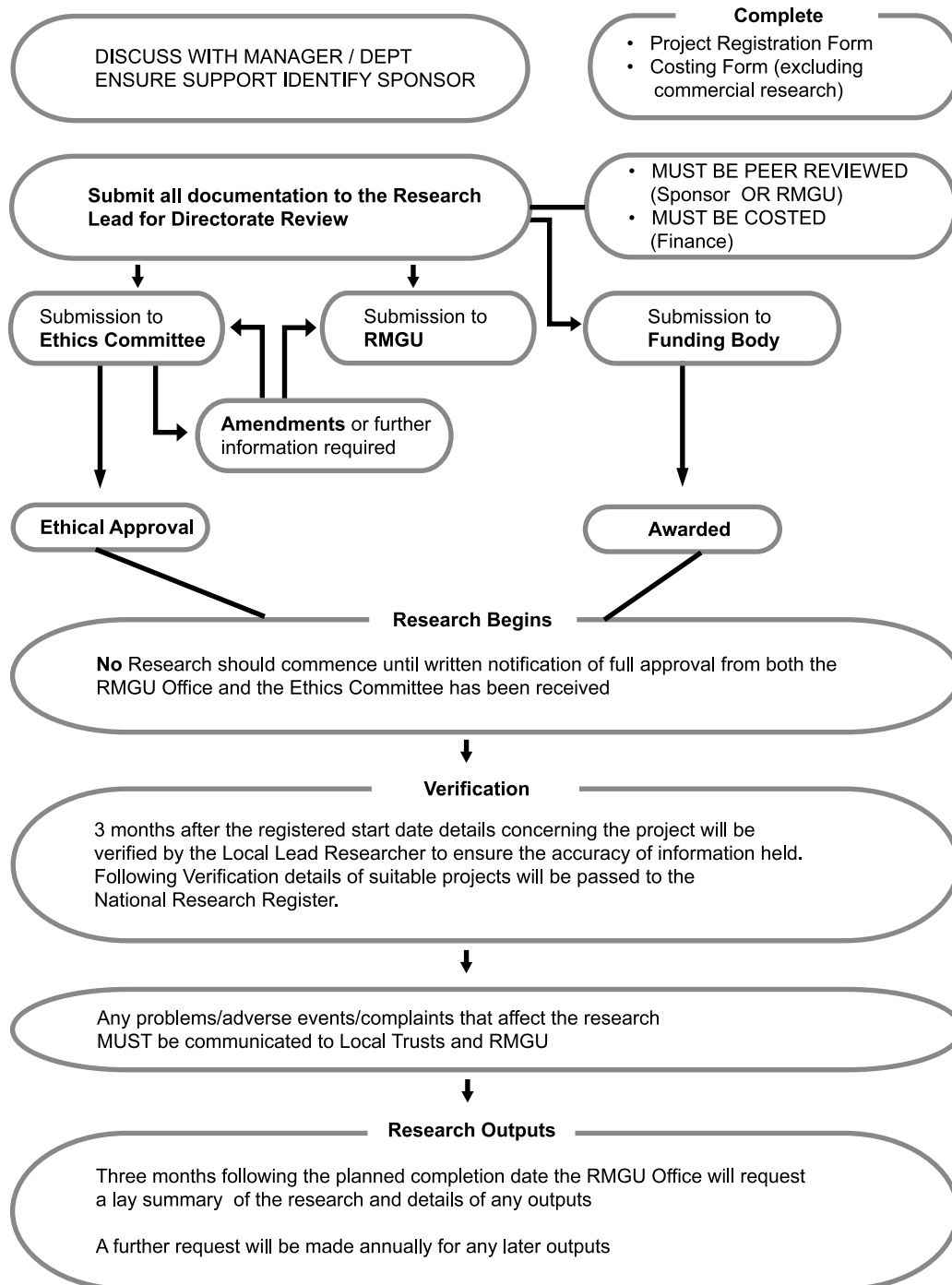
Routine data collection is part of the clinical audit process when it is used to monitor clinical performance (e.g. data from general practice computers and patient surveys). The same activity undertaken to answer a research question would form part of the research process (e.g. morbidity surveillance).

1.4.7 Service Development Assessment

All NHS service development projects should have in-built evaluation that is considered to be audit unless it aims to generate new knowledge.

PCT and RM&G Responsibilities

Pathway for Developing of a Research Project



This process should be followed for both commercial and non-commercial research with the exception of the RMGU Costing Form which is unsuitable for costing commercial trials. Please contact RMGU 020 7594 5536

PCT and RM&G Responsibilities

2.1 Roles and Responsibilities

This section describes the roles and responsibilities of organisations and individuals involved in research activities.

ORGANISATIONS

2.1.1 The Sponsor

Role

The sponsoring body takes overall responsibility for the quality but not for the indemnity of research. Research within the NHS or social care services in England must have an organisation willing and able to take on the responsibilities of sponsor (NB this is currently under review and new DoH guidelines will appear in the new year).

- A sponsor must gain approval from the Department of Health before acting as a sponsor.
- A sponsor may be an NHS Trust, university, charity, or a private company.
- The host academic organisation will normally sponsor student projects.
- When a research team originates from another sector, the sponsor will normally be from that sector.

Brent PCT **will not** automatically sponsor research projects where a potential research project has not found a suitable sponsor.

Responsibilities:

The Sponsor's responsibilities are to ensure that:

- the research proposal respects the safety and well-being of participants and the relationship with care professionals.
- the research proposal is worthwhile, feasible, of high scientific quality and represents good value for money.
- the proposed systems and resources will allow appropriate data analysis and data protection
- arrangements are in place for notification of any significant developments
- dissemination of findings has been planned
- the organisation responsible for ongoing management and monitoring is clearly documented
- there indemnity is arranged
- intellectual property rights are addressed in research contracts or terms of grant awards

PCT and RM&G Responsibilities

2.1.2 Primary Care Trust

A PCT is responsible for all research on its patch. It must know what is going on, inform local researchers of their responsibilities, endorse new projects, and indemnify employees against mishaps. The list of responsibilities is in Section 2 – guide for the PCT research Lead. These include responsibilities of organisations that employ researchers.

2.1.3 Research Management Governance Unit (RMGU)

Its main responsibilities are to:

- Support all local PCTs (except Hounslow) to meet their RM&G responsibilities, and to support them to develop a PCT plan for research
- Monitor research projects passed to it from the partner PCTs
- Amalgamate data provided by Chief Investigators and PCT Research Leads in order to produce annual reports across the sector, and
- Liaise and negotiate with the Strategic Health Authority and Department of Health.

2.1.4 The Host/Care Organisation

Care organisations include general practice, NHS Trusts, the Social Services, voluntary and private organisations. A care organisation has responsibilities when it employs researchers. As well as this it has responsibilities towards employees, patients and/or users and carers that may participate in research.

All care organisations use research irrespective of whether they employ researchers. They are all also likely to participate in research projects from time to time, even if they do not lead it.

2.1.5 The Employer

Role

The organisation that employs a researcher takes responsibility for indemnity unless explicitly stated otherwise. Most researchers on research projects within the NHS will be employed by or through an organisation.

In the case of semi-independent contractors, such as general practitioners, the researcher can negotiate indemnity cover for research that involves their own patients from their professional body; research that involves people other than personal patients is not so covered and it is the responsibility of the Primary Care Trust to agree indemnification of the practitioner.

In the case of independent researchers they must demonstrate that they are adequately indemnified or negotiate an honorary contract with a PCT that is prepared to indemnify that person.

PCT and RM&G Responsibilities

Responsibilities

- Ensuring that any employee engaged in research is adequately indemnified.
- Complying with all current employment and health and safety legislation.
- Ensuring that researchers are aware of, understand and comply with the research governance framework and these agreements.
- Having systems to process, address and learn lessons from any complaints.

2.1.6 Research Ethics Committees

Role

These are independent statutory bodies that include broad representation including lay membership. Any research that involves individuals, their tissue or data must have the prior approval of the appropriate Research Ethics Committee. Their approval is part of the research governance process.

There are three types of Research Ethics Committees (RECs):

- The Central Office of Research Ethics Committees (COREC)
This office has overall responsibility for MRECs and LRECs.
It has responsibility for ethical approval, where required, on international research.
- Multi-centred Research Ethics Committees (MRECs)
Where research is undertaken in more than one Strategic Health Authority and ethical approval is required, it should be request from an LREC in that SHA's area.

Responsibilities

- Facilitating the good conduct of high quality research with benefits for participants, services and society at large.
- The welfare and safety of individual research participants.
- Providing clear and independent advice, within their remit and terms of reference.
- Reviewing advice on the ethical acceptability of a study in the light of progress reports from studies.
- Ethical committees have no legal liability for their decisions and cannot give legal advice. It is the researchers and the NHS or care organisation that have this responsibility.

2.1.7 The Strategic Health Authority

Role

The North West London Strategic Health Authority serves the eight PCTs that are partners to these agreements. Its role is to monitor standards of all aspects of functioning of the Primary Care Trusts, to facilitate joined-up working between PCTs and to advocate for the sector in other parts of government. It therefore must approve the agreements of this manual.

PCT and RM&G Responsibilities

Responsibilities

- to challenge the agreements of this manual where they seem inappropriate and negotiate new understandings
- to facilitate agreements between partners and broker resolution of conflicts
- to facilitate synchronous working of other cross-sectoral functions
- to advocate on behalf of the Steering Group in other places
- to understand local realities, rectify inequities, solve problems and take advantage of new opportunities
- to critique progress and facilitate useful comparison with other places.

2.1.8 The West London Primary Care Research Network (WeLReN)

Role

WeLReN is a network and therefore has the particular strength of facilitating relationships across boundaries. It has modest funds for small-scale research projects, for academic support and for building research capacity. It shares with other partners to this Consortium the three aims to: a) undertake research projects appropriate to primary care; b) build research capacity; c) support the development of a reflective and inquiring culture.

Responsibilities

- to use its funds wisely to develop research appropriate to primary care including building multidisciplinary research capacity.
- to further understandings of organisational approaches that further these aims.
- to support members of the Consortium with the development of their plans for research and development and to help them to solve problems.

2.2 Individuals

This section describes the roles and responsibilities of named individuals other than the PCT Research Lead and the director of the RM&G that are implied from the organisational roles described above:

2.2.1 Chief Investigator (CI)

Role

Every study must have designated a Chief Investigator (CI) who takes overall responsibility for the clinical component of the study, or the interface and interaction with patients, records, or staff. There can only be one CI in the eyes of the RM&G office, even for research across more than one site.

PCT and RM&G Responsibilities

Responsibilities

- the design, conduct and reporting of the study and appropriate liaison with other researchers
- ensuring that the research question is the most appropriate given the context and the proposed project is feasible, useful, safe, legal, ethical and financially appropriate
- ensuring that the project has the approval of the local PCT, the Ethics Committee and the Sponsor
- providing quarterly progress reports to the RM&G office via e-mail, including monitoring of progress with the agreed project timeline, and the prompt production of any other agreed reports
- ensuring that the dignity, rights and well-being of participants are respected and informed consent is gained
- ensuring that care professionals are informed when their patients/clients are invited to participate, agreeing that they retain overall responsibility for their care and ensuring that feedback about the care of participants is passed to the usual care practitioner, unless there is specific agreement otherwise
- being accountable for the conduct of research problem-solving and ensuring that those working on projects have necessary expertise or supervision
- ensuring that the approved protocol is followed and that any significant changes to the protocol are appropriately negotiated and submitted to the ethics committee and the research sponsor for approval
- implementing procedures to ensure collection of high quality, accurate data and the integrity and confidentiality of data during processing and storage
- ensuring findings are open to critical review and significant findings are published within a reasonable time
- ensuring that all data and documentation are available for audit and ensuring appropriate archiving of data at the end of the project
- ensuring good financial and resource management of intellectual property
- ensuring that controlled trials have been registered.

2.2.2 Researchers

Role

Researchers are those involved in the research project that interact with participants, their data or tissue, or that test equipment on or issue trial medicines to participants.

Responsibilities

- remaining in ongoing communication with the Chief Investigator and taking their agreed role in the team
- ensuring that protocols are rigorously followed and no changes are implemented without appropriate agreements
- ensuring that participants understand what is asked of them
- communicating with those responsible for the healthcare of the participant
- feeding back results to participants where agreed
- ensuring that the data collected is accurate and kept secure
- coding data to ensure that information that identifies participants is kept separately from other data
- disseminating results via the peer-review process
- reporting any adverse events or misconduct.

PCT and RM&G Responsibilities

2.2.3 Participants

Participants of projects are those who are the object of the research. They may be patients, staff or the public.

2.2.4 Consumer representatives

All research involving patients, staff, their tissue or data for which the NHS is responsible must involve consumer representatives at appropriate parts of the design and conduct of the project.

Summary of the Key Responsibilities of People and Organisations Accountable for the Proper Conduct of a Study

Principal Investigator and other researchers

- Developing proposals that are ethical and seeking research ethics committee approval
- Conducting research to the agreed protocol and in accordance with legal requirements and guidance e.g. on consent
- Ensuring participant welfare while in the study
- Feeding back results of research to participants

Research Ethics Committee

- Ensuring that the proposed research is ethical and respects the dignity, rights, safety and well-being of participants

Sponsor

- assuring the scientific quality of proposed research
- ensuring research ethics committee approval obtained
- Ensuring arrangements in place for the management and monitoring of research and for indemnity

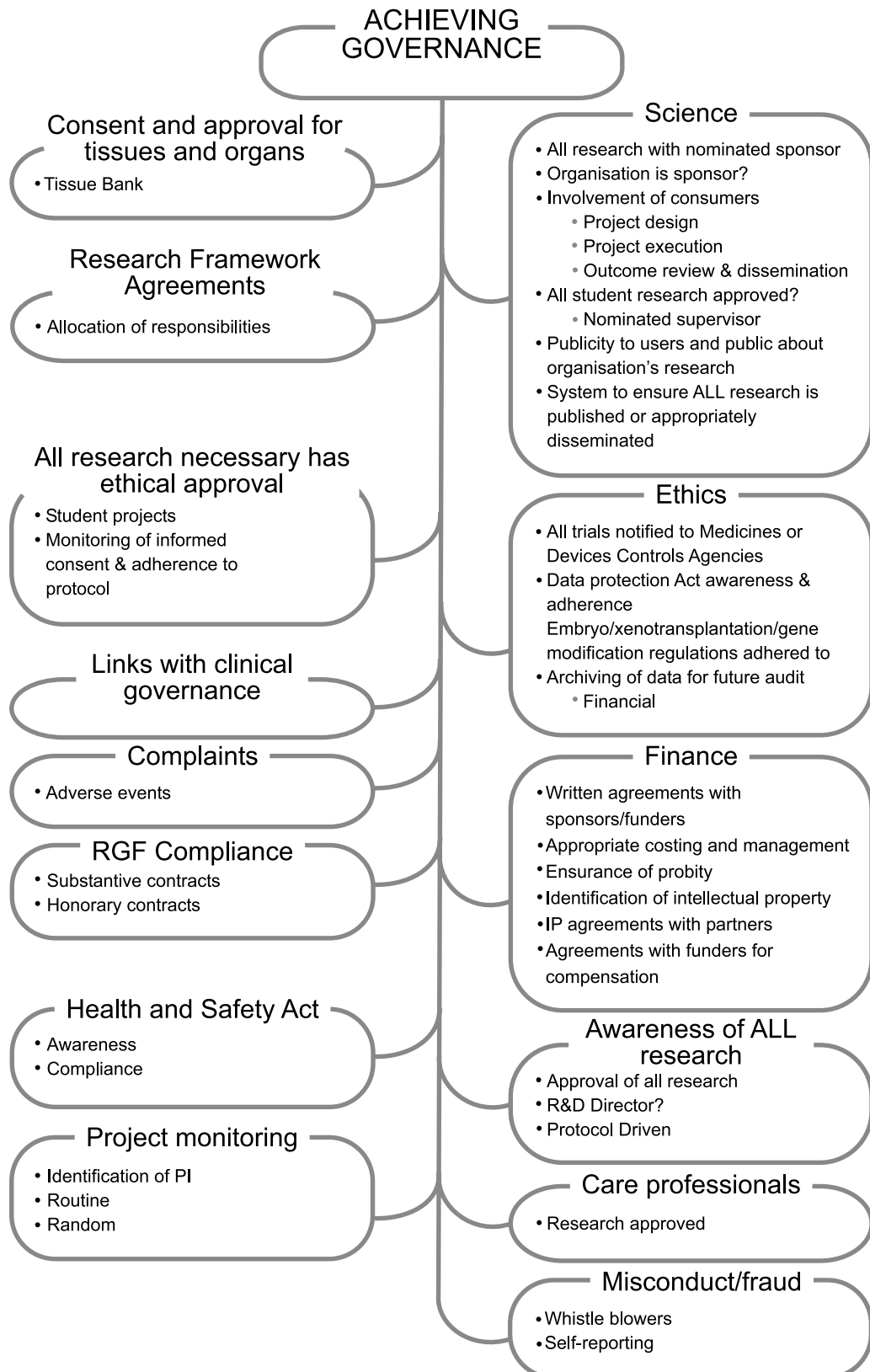
Employing organisation

- promoting a quality research culture
- Ensuring researchers understand and discharge their responsibilities
- Taking responsibility for ensuring the research is properly managed and monitored where agreed with sponsor

Care organisation / Responsible care professional

- Ensuring that research using their patients, users, carers or staff meets the standard set out in the RGF (drawing on the work of the research ethics committee and sponsor)
- Ensuring research ethics committee approval obtained for all research
- Retaining responsibility for research participants' care project

Research & Governance Protocols



Research & Governance Protocols

3.1 Overview of the Process

- STEP 1** The named Research Lead for a PCT is the point of local contact. He /she is responsible for informing his/her local PCT of its responsibilities about research and to update them of emerging opportunities and threats. This person secures home PCT endorsement for a locally developed project and passes its details to the RMGU. Usually the home PCT will also be the Sponsor.
- STEP 2** Where appropriate, the RMGU, in collaboration with the home PCT, will arrange a peer review of the proposed project. The Chief Investigator applies for Research Ethics approval and sends a copy to the RMGU. Once approval is received from the LREC, the RMGU informs the National Research Register. Where possible a copy of the LREC approval is sent directly from the LREC to the RMGU and to the sponsoring PCT.
- STEP 3** On a quarterly basis the RMGU e-mails the Chief Investigator of the project(s) for an update on progress against the project timeline. Support with emerging problems is the responsibility of the home PCT, but they may wish to invite help from others, including the West London Research Network. In February of each year this data will be amalgamated by the RMGU to provide analysis by PCT and sector to show the evolving pattern of engagement in research by discipline, geography and research approach.
- STEP 4** In January of each year all PCTs (including Hounslow) will undertake an e-mail survey with the help of the RMGU of all research active practitioners. This will establish the impact of research activity of the previous calendar year, including a) publications and presentations about research, b) the benefit as perceived by the researchers, and c) unexpected developments. These provide the year-on-year record of the local impact of research.

The PCT Research Leads will meet as a learning set on a quarterly basis. This group will share new insights and negotiate new agreements.

Research & Governance Protocols

3.2 Phases of the process

The research governance process is in three parts:

- 1 Approval**
- 2 During research activity**
- 3 Post research**

3.2.1 Approval process – New Projects

Research will need to be endorsed by individual PCTs in the first instance. Where there is no external sponsor, Brent PCT may provide a sponsor role. The procedure for endorsement is indicated by the flowchart (see appendix):

3.2.1.1 Approval Checklist

The following are needed for approval (informal discussion of issues can be done at any point to avoid repeated complete re-application):

- protocol
- information sheet for participants
- peer/independent review process
- example of consent form
- start date and expected duration
- parties involved (see below)
- venue details
- contracts and agreements between parties

Contact and other details must be obtained and recorded for the following:

- sponsor (or Supervisor - in the case of student projects)
- Chief Investigators and their organisations - including their qualifications and selection criteria
- ethics approval application and committee to which the application is to be sent to
- care organisations involved
- indemnity details (for all research staff including freelancers)
- funder and financial details (budgets etc)
- intellectual property arrangements and agreements
- consumers involved in the project
- research organisations

CI's or Sponsors should also consider the following:

- procedures for adverse events
- health and safety arrangements
- arrangements for record keeping, and storage of data during and after project
- financial systems/payment of relevant costs

Research & Governance Protocols

3.2.2 Conduct during research activity

The Research Governance Framework for Health and Social Care indicates that the following principles are observed and maintained:

3.2.2.1 Informed consent

- Researchers must give patients/staff, their guardians and/or carers written information about the study prior to gaining their written agreement, which must be obtained, before prospective participants may be researched.
- Consent and information on the study must be copied to the patients' GP, or where staff members are subjects, to the relevant Human Resources/Personnel department.

3.2.2.2 Adverse events

Adverse Event

Any untoward occurrence in a patient or clinical trial subject and which does not necessarily have a causal relationship with this treatment. (2001/20/EC)

Serious Adverse Event

Any untoward medical occurrence that at any dose:

- Results in death;
- Is life threatening (the subject was at risk of death at the time of the event);
- Requires inpatient hospitalisation or prolongation of existing hospitalisation;
- Results in persistent or significant disability/incapacity; or
- Is a congenital anomaly/birth defect (2001/20/EC)

All adverse events occurring to trial participants must be reported to the Trust's Research and Development Directorate within the time scales listed below.

Please report all Serious Adverse Events on the day of occurrence either by phone or deliver this completed form by hand to the Research Governance Facilitator at the address below.

* If you advise R & D by phone, please ensure a completed form is delivered within 48 hours.

Non-serious Adverse Events

Please report all Non-Serious Adverse Events to the R & D department within 7 working days of occurrence.

Research & Governance Protocols

3.2.2.3 Negligent and Non-negligent harm

3.2.2.4 Data protection and Record keeping

The Data Protection Act 1998 came into force in 2000. The principles of the 1984 Act remain unchanged although a major development is that the legislation now covers paper records as well as electronically and magnetically recorded material. The definition of “processing” is also wider than that in the 1984 Act, and includes the concepts of obtaining, storing and disclosing data.

What is Personal information?

Personal information is all information about individuals, living or dead. For example medical records which are written or held on a computer system, images, recordings or such information

Personal data has a narrower definition and is more closely concerned with avoiding the possibility of identification. It is information about living people which in isolation or in combination with other data which may be available, may lead to the identification of the patient.

Confidential information in the context of healthcare, is information about oneself given on the explicit or implicit understanding that it will not be disclosed to others outside the patient’s care, without the patient’s consent. Both the law and patients assume that this is the case when personal information is disclosed as part of clinical care.

Sensitive information refers to information about individuals which may have particularly deleterious effects if it is disclosed inappropriately. The Data Protection Act 1998 refers to ‘sensitive personal data’ as including all information about physical or mental health or condition, or sexual life.

Coded data is not anonymous data. Identities are disguised by the code but the code can be easily decoded by those in control of the data. For example, an ‘alphanumeric code’ made up of a patient’s postcode/initials and date of birth is not anonymous. Informed consent from the participants is required for this situation (except in exceptional situations where the need is waived by applying to the Department of Health).

Anonymised data is data which has been coded by others outside the research team, for example from a national database such as the Cancer Registry or a large pharmaceutical company. Permission for this data to be used in future research should be requested at the time of initial consent to registration or research.

Linked Anonymised data can be decoded by the organisation supplying it to the researchers but not by the researchers themselves. For example a Care Organisation may need to link perhaps unexpected research data to a particular patient in the interests of their care. Informed consent from the patient is sometimes necessary when using linked anonymous data. The Research Ethics Committee should be consulted.

Unlinked Anonymised data describes the situation where the link between the data and the person to whom it refers has been irreversibly broken. No one could use this data to identify a specific individual. Informed consent is not necessary for research which makes use of unlinked anonymised data.

If you are using and / or holding personal information as part of your research, you must complete a Data Protection Act form.

Research & Governance Protocols

3.2.2.5 Reporting and accountability

- The Chief Investigator must account for and explain activity, purpose and report progress to the public and participants.
- The Research Governance Unit must be informed of any publication that results from research it has given approval to, and be given a copy.
- The Research Governance Unit may be able to assist with dissemination.

3.2.2.6 Audit of Research Projects

- All parties to research must assist and fully co-operate with the RMGU.

3.2.3 Post-research process

3.2.3.1 Data storage

The validity and confidentiality of data is paramount on the completion of a project for the research to protect the participant's details and for the findings to be verifiable. On the completion of the project, the Chief Investigator should discuss with the RMGU and the Sponsor how the data gathered will be stored.

3.2.3.2 Reporting

Chief Investigators are responsible for:

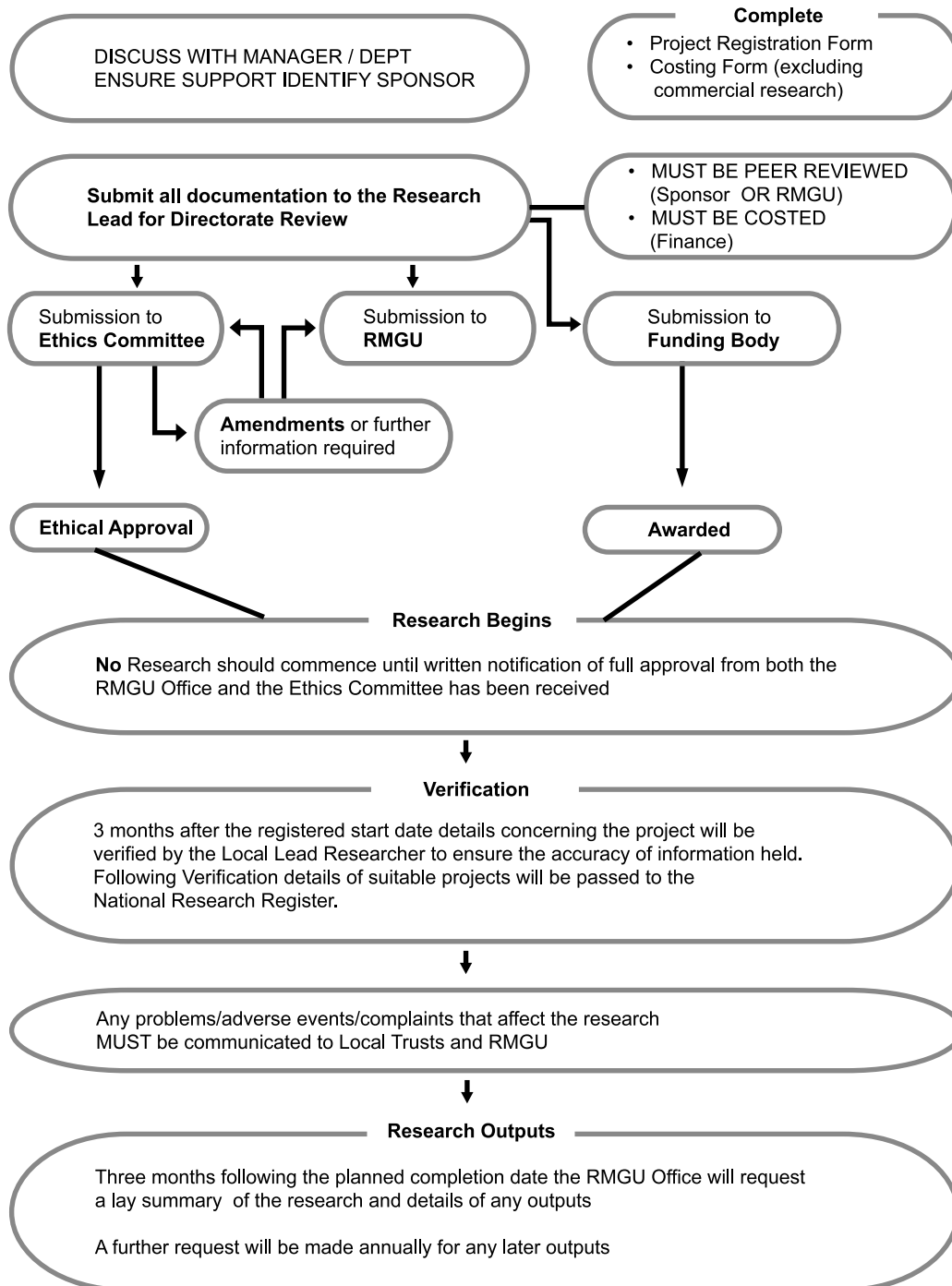
- Producing and providing reports of the findings of the project, that are accessible, useful and relevant to participants, other parties to the research and the public.
- Co-operating to submit findings to the National Research Findings electronic Register

3.2.3.4 Intellectual property

Any project where the NHS has a right to intellectual property should be exploited as far as possible in order to maximise the commercial potential of the project.

Research & Governance Protocols

Pathway for Developing of a Research Project



This process should be followed for both commercial and non-commercial research with the exception of the RMGU Costing Form which is unsuitable for costing commercial trials. Please contact RMGU 020 7594 5536

Research & Governance Protocols

3.3 Ten Easy Questions for the Investigator Aspiring to Undertake Research in Primary Care

3.3.1 Is what I am proposing to do 'research'?

Having consulted the definition of 'research' adopted by the DoH (summarised at 1.4.1), if the answer is NO, the RGF for primary care does not apply. It may be that the proposed enquiry is actually a 'clinical audit', in which case oversight more properly should come from the local clinical governance system. It could also be that the proposed project is neither 'research' nor 'clinical audit', but something else entirely. If the answer is YES, the proposed project meets the definition of 'research', go to Question 2.

3.3.2 Am I an 'accredited primary care investigator' (an ACPI)?

A system for identifying and accrediting individuals who are authorised to conduct research in primary care is still being devised, but the likely qualifying criteria are likely to be that the individual meets at least one of the following:

- a. He or she has been accredited to undertake research in primary care by an appropriate professional body such as the relevant Royal College;
- b. He or she has completed a higher degree (at Masters level or above) that included some original research based in primary care;
- c. He or she is the first author of a peer-reviewed scientific publication based on original research in primary care.

In part the ACPI system is being deliberately designed to establish a hurdle to hospital-based and other external investigators who, perhaps despite considerable seniority and experience in their chosen fields, often have no experience in undertaking research with free-living individuals in their own home communities.

If the answer to the question regarding an ACPI is NO, the individual either has to find a partner in the research who is one, or obtain status as an ACPI in his or her own right.

If the answer is YES, and the proposed project meets the definition of 'research', go to Question 3.4.3

3.3.3 Is there a written protocol for the research?

All research must be supported by a written protocol that sets out the rationale for the enquiry and describes how it is to proceed. It can be anticipated that systems of Research Governance will shortly insist that peers of the investigator(s) have first subjected all research to scientific review. A written protocol is a necessity for meeting this standard, but also generally provides a good discipline in requiring the investigator to specify exactly what is the question to be addressed by the project, and to select and defend the methods for answering it.

Research & Governance Protocols

3.3.4 Has ethical approval been obtained for the project?

Under current guidelines from the European Community and the Central Office for Research Ethics Committees (COREC) all research undertaken in the NHS that involves patients, tissues or records, including that undertaken by students, requires clearance from a Local Research Ethics Committee. Coupled with moves to abolish the provision for approval of non-sensitive projects via 'Chairman's action', and to impose a maximum of ten applications to be considered at any given meeting of an LREC, one can be confident that the system for ethical approval will slow from its present snail's pace to a complete halt, but the principle that most research undertaken in the NHS requires ethical review of some kind is most unlikely to be amended significantly.

At present, research that will be limited to one Strategic Health Authority area needs approval from one LREC within that area. If appropriate, other LRECs are informed of the project via a 'locality' process in which the investigator submits to each such committee a copy of the original LREC application, a copy of the written protocol for the project, and a copy of the original LREC's determination as to the acceptability of the study.

Rules regarding projects that cross more than one Strategic Health Authority area are presently (September 2003) in transition. Under the existing system, projects involving five or more such areas have to be submitted in the first instance to a Multi-centre Research Ethics Committee (MREC). It is proposed that this will be replaced, before the end of 2003, by a threshold of three Strategic Health Authority areas.

3.3.5 Who needs to know about this project?

The advent of more rigorous RM&G in primary care imposes a further duty of notification on the would-be investigator in that his or her local 'research lead' within the PCT must be informed that the study is to take place, and provided with a copy of the ethical approval.

There is some discussion, in relation to connections between 'research' and 'clinical governance' for example, and the activities of the Commission for Health Improvement (CHI) and its successor, that this interaction with the local PCT should go beyond 'notification' to 'approval'. Furthermore, approval by the PCT might be made contingent on a demonstrable link with local and national priorities, the latter reflecting the National Service Frameworks, for example.

Such thinking represents a push of the pendulum firmly towards 'strategic research' and away from 'investigator-driven research'. The appropriate balance to be struck between these is continually contentious, but significant and sustained deviations from the vertical in either direction are probably not in the community's best interests, because the one tends to suppress major innovation, while the other threatens an anarchic free-for-all in which it can be very difficult to identify what may represent good value-for-(public)-money.

Rules regarding notification of multiple PCTs where a research project involves patients or records in more than one Trust have yet to be developed. The guiding principle, however, is that all relevant authorities need to know that the research is taking place and which NHS organisation has accepted responsibility for ensuring that good practice will be followed throughout the process of the investigation.

Research & Governance Protocols

3.3.6 Do I need an Honorary Contract?

Where a research project involves a PCT with which none of the investigators has a formal affiliation, it is likely that at least one of them will require an Honorary Contract with that Trust. From the viewpoint of the NHS, one of the investigators having status as an ACPI is not enough, because this does not formally bind that individual to follow good research practice. All new contracts and honorary contracts with staff of the NHS will include a provision that any research undertaken by that individual is conducted in accordance with accepted rules of good research practice.

In regard to research, the quid pro quo of an honorary contract is that it also formalises the responsibility of the issuing Trust to ensure that good practice is followed in all research.

3.3.7 What other paperwork do I need to have?

Thus far these notes have identified the need for:

- a. A written protocol
- b. Approval from relevant ethics committee(s)
- c. (Evidence of) notification of relevant PCT(s)
- d. Appropriate contracts or honorary contracts with NHS organisations.
In addition, the principal investigator leading a piece of research has a responsibility to keep:
- e. A record of all participants in the research, all medical records inspected, and all tissue specimens collected, analysed or stored
- f. Evidence of consent from individual subjects to their participation, where collection of such consent was required
- g. A register of all genetic material collected and stored in the course of the research
- h. A register of withdrawals from the research, with relevant dates and reasons;
- i. A copy of the original data and the statistical and other analyses on which reports prepared for publication were based
- j. A register of adverse events, whether clinical, laboratory or ethical.

The list of participants in the research is required because new systems for RM&G include provision for an independent interview with participants regarding recruitment to, and conduct of, the project.

Standard advice is that records of research projects, including relevant data and analyses, should be maintained for at least seven years after the project is completed and the results published, whichever is the later. This period is based on the usual 'statute of limitations' in civil law, but medical defence organisations regularly advise that obstetric records should be maintained for at least twenty-one years, suggesting a similar policy for (interventional) research involving pregnant women.

Research & Governance Protocols

3.3.8 Who is 'sponsoring' and indemnifying the research?

This question supplies the answer to another less formal one, 'who will carry the can, should something go wrong and a complaint be made?' Clearly, the responsible investigator will always be a respondent to official complaints, but consumers will also want to know which organisation apparently permitted a research project to be conducted in what they regard to be a sub-optimal fashion. The NHS or other organisation that accepts responsibility for ensuring that breaches of good research practice do not occur is the 'sponsor' of the research and would normally be expected to provide indemnity cover for those conducting the study.

3.3.9 Who is the financial sponsor of the research?

The sponsor of a piece of research, in the sense described by Question 3.4.8, is not necessarily the same entity as the one that is funding the research. The distinction is seen clearly in many drug trials, where a commercial entity with an obvious vested interest in the medicine commissions an independent entity such as a charitable research foundation to conduct a clinical trial of the product. In such instances, the foundation acts as guarantor of the intellectual propriety of the work. However, if the trial is based in a particular clinical unit, the NHS entity in which that unit is located may well be the 'sponsor' of the project, in the sense of Question 3.4.8, in that it will be a co-respondent should a participant suffer a misadventure or make a complaint about the study.

3.3.10 What are my responsibilities in regard to reporting?

Ethics committees and financial sponsors will have their own requirements in regard to reporting. Rules regarding routine reports to NHS entities acting as sponsors for research in primary care are still being developed. However, the guiding principle is that investigators should alert the sponsor quickly should a complaint or significant adverse event occur in the course of the research. This goes right back to the idea of CEOs of PCTs not having any 'nasty surprises' arising from research being conducted on their 'patch'.

Appendix

IN DEVELOPMENT PHASE

Forms and guidelines

Over time a number of guidelines will be issued and incorporated in the handbook. It is anticipated that this will reflect the changes taking place within research governance and continuous refinement of the system. Attached are a few examples for considerations

Appendix

Honorary Research Contract

I am pleased to offer you an Honorary Research Contract in association with Brent PCT in the Applied Research Unit within the Public Health Directorate based at the Wembley Centre for Health and Care.

It began on _____

and will continue until the completion of your project called _____

_____ and carries no remuneration with the Trust.

In accepting this association, you will be accountable to Brent PCT for the execution of any research and agree to conduct all research in compliance with the Research Governance Framework for Health and Social Care as specified by the Department of Health.

I am enclosing two copies of this letter and I would be grateful if you could confirm your acceptance of this association by signing one copy and returning it to:

Terms and Conditions

1. Purpose of the attachment

You will be attached to Brent PCT for the any purpose of research projects.

2. Location

You may only attend locations in your capacity as a researcher that are of relevance to the project indicated.

3. Period of attachment

Your period of attachment will be for the period indicated above.

4. Professional accountability

For the duration of your attachment you will be responsible to the research sponsor organisation, and the Primary Care Trust for the area in which you are working. If there is no specific sponsor other than Brent Primary Care Trust then the sponsor is Brent Primary Care Trust and you will be accountable to the Director of the ARU.

5. Confidentiality

It is essential that information to which the post-holder has access regarding both patients and staff should be treated in the strictest of confidence. While working for on the research study you will be expected to become familiar with the Trust's confidentiality policies and procedures and

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agree to abide by them. Failure to observe confidentiality constitutes gross misconduct. This is liable to disciplinary action. This is in accordance with the Data Protection Act 1984 and the Health Records Act 1990).

6. Non-compliance

In the event of Brent PCT receiving evidence of non-compliance with the Research Governance Framework then your contract may be terminated without adjudication. In the event of allegations of serious misconduct being made you may be required to leave the Trust's premises pending investigation.

7. Health and safety at work

The Health and Safety at Work Act 1974 requires that you have responsibility to take reasonable care for your own health and safety and for that of other persons who may be affected by your own actions or omissions for the period of your attachment with the Trust/University/Practice.

8. Fire precautions

It is essential that you ensure that you know the fire precaution arrangements in the Trust/University/Practice premises.

9. Sickness

If for any reason (such as sickness) you are unable to attend for the purpose of your attachment you should inform your supervisor as soon as possible.

10. Termination

This contract/attachment can be terminated by either side on notice of four weeks.

11. Insurance for property

The Trust does not normally accept responsibility for articles being lost or damaged on Health Service property as a result of burglary, fire, theft or otherwise. You are advised accordingly not to bring items of value to your place of work, and to provide your own insurance cover.

12. Acceptance and understanding of conditions relating to this attachment

I have read and understood this document and agree to abide by its terms:

Researcher Confirmation of acceptance

Date _____ Signed _____ Name _____ Position _____

Date _____ Signed _____ Name _____ Position _____

Appendix

Project Registration Form

The form should be completed by anyone proposing to carry out research involving primary care patients or staff in North West London. The details requested are those required under the Department of Health's Research Governance Framework and by the local Primary Care Trusts for their project database. For further information, please contact XXX at the Research Management Governance Unit (RMGU).

Section 1: Contact Details

Name of person completing the form

Title of the project

If the research project is being undertaken as part of an educational course or degree, please state the name of the programme and HEI and then go to section 2.

Name & Title of Lead Researcher
Full contact address
Telephone number
E-mail address
Approximate time (sessions per week) to be spent on the project

Please state in the box below the details of any staff employed by any of the PCTs in NW London (except Hounslow) who may be involved in this research and an approximation of the time they will spend on this project each week.

Name	Job Title project (sessions per week)	Estimated time spent on

Appendix

Section 2: Academic Research (Please complete and then go to Section 3)

Name of academic institution and unit/department _____

Name of supervisor for the project _____

Contact details for supervisor _____

Section 3: Details of your project

1. What is your research question or the main aim of your project?

2. What population will you be studying?

3. Please briefly describe the design of your project under the headings below:

Method (i.e. what are the main methods of enquiry to be used?)

Main variables of interest (i.e. what are the specific features or characteristics of what you are studying that are of most interest to you?)

Outcome measures (i.e. how are you intending to measure or assess the variables of interest?)

4a. Is this research in partnership with another organisation? Yes No

4b. Is it part of another project? Yes No

5. Briefly indicate how your project is relevant to the service objectives of the Trust or the Trusts in the area(s) you are working, or describe how the project is addressing the needs of the local population. (Projects must be able to demonstrate that they have engaged with primary and community care practitioners in the PCT(s) within which they propose to work and that there are agreed benefits of the study to those practitioners)

6. Please state the estimated start date and completion date for this project

From:

To:

7. How do you plan to disseminate the findings from your project?

Appendix

Section 4: Research Governance - Essential Requirements, 2002/2003

Does your project require ethics committee approval?
Please see guidelines from RMGU for more information

- Yes (please go to Q2) No (Please go to Q3)

2. If your project does require ethical approval, has this been obtained?

- Yes Name of LREC (Please attach a _____ copy of the approval documents from the ethics committee)
- No, not yet applied
- Waiting to hear decision from the ethics committee
(Please forward us the documents after approval is received)

3. If your project does not require ethics committee approval, please state the reasons for this.

4. The Research Governance Framework strongly emphasises that projects utilising patient identifiable data must adhere to the Data Protection Act (1998). Please briefly indicate how you intend to protect the data collected in this project.

5. The framework also draws researchers' attention to the importance of health and safety within the research environment. Please briefly indicate any potential health and safety issues, for either researchers or research participants, that may arise from your project and how you intend to address them.

6. Within the research governance arrangements all projects are required to make provision for the fully informed consent of research participants to be obtained. Emphasis is also laid on researchers' monitoring how consent procedures are implemented during the project. Please indicate what arrangements you are making for obtaining informed consent, (enclosing a copy for our records of any consent form that you have submitted for approval by the ethics committee) and state how you will be monitoring the implementation of those arrangements.

(The RMGU can be contacted for an example consent form and further information on consent)

Section 4:

Appendix

Signed by lead researcher/project manager
Date

Please return this form to: Research Management Governance Unit/WeLReN, Dept of Social Medicine and Primary Care, Imperial College, Reynolds Building, St Dunstons Road
Tel. 020-75945536

For R & D Office use only
Project Registration Number _____ Date form received _____
Date first considered by RMGU _____ Date approved _____

Appendix

GUIDANCE NOTES FOR WRITING PROTOCOLS

This is a guide to writing research protocol. It is intended for the novice researcher and may be useful for others as a checklist.

It is advisable for individual researchers to work closely with an expert in the field who will be able to provide advice on study design, power calculations and data analysis. Help on these matters is available from the Research Department Statistician.

Assistance on study design can also be obtained from the WeLReN office as can assistance with costing, realistic estimates of recruitment, proposed milestones and project management. The Department of Primary Care and Social Medicine at Imperial College may also help to find collaborators from other disciplines to strengthen both the proposal and the research team.

Please note that research applications often fail because of one or more of the following:

- There is inadequate clarity surrounding the main research question
- The proposed method is unfocussed
- Lack of adequate information about statistical information
- Lack of involvement of appropriate experts in the design of the project
- Unrealistic timescales and costing

GUIDANCE

Section 1: Details of lead applicant

This should be the name of the person who will be undertaking the study and the individual to whom all correspondence about the application will be addressed. You should give an e-mail address and telephone number. In the case of student research, both the name of the student and the supervisor needs to be included.

Section 2: Title of project

The title should be the same as that of your application to the Local Research Ethics Committee.

Section 3: Project reference number

This refers to the number accorded your project when you registered your intent to carry out a project with the Research Department. Please note that failure to register your project will delay your application process.

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Section 4: Research question(s)

Is there a clearly defined, answerable, research question?

- **Main research question(s):** give a formal statement of the precise question the research is intended to answer and/or the hypothesis it is intended to test. It is important to focus on a single main question. For example, does the project concern itself with all the sufferers of a particular condition, or only with a sub-set? Do not feel that you have to address the total service problem, but be clear about the part you are going to address. Distinguish the key prospective question(s) to be answered, from the data set to be collected, as distinct from potential use of the data to carry out retrospective analysis. How generalisable will your results be?
- **Secondary research question(s):** this should be any subsidiary question(s) within the main aim, which the research is intended to answer. Where there are secondary questions, it would normally be expected that these would be few in number. Lack of focus within a project, through trying to address too many aims or collect too wide a range of information, is a common problem and can prevent any useful results being obtained.

Section 5: Background

Clinical and scientific relevance: Is the research question an important one - i.e. is there a real clinical problem here, or a gap in knowledge, which needs filling? Indicate that a thorough review of research in this area has been undertaken.

You need to state clearly the benefits, both to patients and to the NHS, that would follow if clear results were obtained and subsequently applied. You should say explicitly what the potential practical value would be of the results of your research.

It may be that there will be no potential for direct clinical impact from your project. For example, the results may form the basis for further research that will have benefits in the future. If this is the case, it should be clearly stated as well as the way in which further research would be able to build on your results.

Scientific justification

In this context, 'scientific' is a broad term and indicates a rigorous, systematic approach rather than defining a particular category of research.

Student research needs to conform to university regulations in terms of the originality of the study.

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Section 6: Plan of investigation

Methodology:

You should describe and justify your methods in some detail – what you will do, how you will do it and why you have chosen this approach. Are the proposed methods appropriate - will they address the question being asked, are they likely to produce a useful answer, are they designed to reduce the risk of bias?

Feasibility:

Acknowledge any specific difficulties faced by the research. All research is difficult. Failure to recognise, or acknowledge potential difficulties could be to your detriment in successfully completing the project. Potential obstacles could include problems with measurement, methods of describing case-mix, uncertainty of recruiting or finding the necessary numbers of cases. Don't dwell on potential problems, but make sure that the referee knows that you have thought of them and have taken them into account.

- The nature of **the design** adopted (e.g. randomised controlled trial, cross-over study) must be clear and explicitly justified as an appropriate one, i.e. suitable to answer the question or test the hypothesis posed.
- If you are carrying out a **statistical analysis**, you should describe what the analysis is intended to do (e.g. you may intend to make a comparison between groups of the proportions of individuals satisfying particular criteria, or you may want to compare the mean values of a quasi-normally distributed variable before and after an intervention). You need to think at this stage about what steps you will take to ensure data integrity, what percentage of data you might expect finally to be missing, what arrangements you will make both to minimise this and to ensure accuracy and how missing data may affect the analysis, both in terms of attrition/power and in terms of selection or reporting bias.
- **Outcome measures:** you should describe what will be measured, and how, to show whether or not the question has been answered. If you propose to include general or specific measures of health status before and after an intervention to measure health outcome/gain, you should ensure that you obtain appropriate advice on how to do this, indicating the instruments to be used and brief evidence of their suitability.
- **Setting for the project:** where will the project be carried out? Is the setting appropriate - e.g. if you plan to do your study in an outpatient clinic, is this the best place?
- **Participants:** Will the proposed **sample size** be appropriate to obtain meaningful results? You need to state what your sample consists of, how you have identified it and why.

Will the sample be representative of the population? Details of the inclusion and exclusion criteria should be given.

You should give the basis on which you have calculated the required sample size, e.g. which outcome variable has been chosen on which to base the power calculation and why? How was the adopted estimate of variability arrived at - from the literature, from a pilot study etc? How did you arrive at the benchmark of what should be considered a clinically - or otherwise - useful effect? What probability and power levels have been adopted?

Exceptionally, if your study is preliminary, descriptive or uses methods which do not require this, say so explicitly and why.

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- **Recruitment:** How will you identify, approach, recruit and consent your participants? Is it likely that there will be problems in obtaining the numbers required for the study, whether this is patients, clinics or tissue samples? Check that estimates of recruitment of participants are realistic and that your proposed milestones can be met. One of the major problems faced in research projects is failure to obtain as many samples/participants as the researchers initially anticipated.
- **Intervention:** Detail the intervention, where this is appropriate to the study, indicating clearly the participant's involvement throughout the course of the study. COREC suggests the use of a flow chart.
- **Instruments:** The suitability of the instruments you propose to use must be established, e.g. are they sufficiently sensitive to pick up variation in the particular target population(s)?

Any **unusual or novel** techniques, or those originating in disciplines remote from medicine, should be justified at slightly greater length.

If you propose to include **service costing data**, then ensure that you obtain appropriate advice on how to do this, indicating clearly the degree of accuracy and representativeness you wish to claim for this data.

Section 7: Project plan

Is the estimated duration of the project appropriate? You should give a work plan, which lists the main stages and targets within the project and a timetable for completion of each phase of the work, including analysis, write-up and dissemination.

If your application is supported, the project plan will be used as an aid to monitoring progress of the project.

A diagram is often helpful.

Section 8: Project management

Indicate how you intend managing the project to ensure that it delivers its intended outcomes on time. What review and reporting mechanisms will you be using?

Section 9: Expertise of the researcher and associated team

Explain how the team possesses sufficient expertise to deliver a successful outcome.

- Are you in a good position to carry out the particular piece of work? For example, you may have previous experience of the field, have already carried out a pilot, have baseline data already available, have access to an adequate supply of patients.
- Does the research team either include people with expertise in all the areas of work required by the project, or have access to people with the relevant expertise at the appropriate points in the project? Do you have assured support from clinical and/or professional colleagues and have access to required facilities?

Appendix

Section 10: Ethical issues

Is the proposal ethically sound? Are there particular ethical issues that may arise in a project of this nature?

Explain how you have addressed the following questions: are the participants protected from undue risk? Are their rights to information, confidentiality and privacy respected?

Section 11: Involvement of service users

Indicate the level and nature of any involvement in the planning, conduct and/or dissemination of your project by service users.

Section 12: Methods for disseminating research results

The research programme for which the STH Trust acts as Sponsor is in the public domain and the Research Department may publish details of the research project in any report or presentation of the Trust's R&D Programme. All non-commercially funded projects are included in the National Research Register, which is widely available across the country, and can also be accessed on the Internet (www.update-software.com/national).

The results of research undertaken with Trust resources are expected to be submitted for publication by the researcher. You should therefore include a short account of how you plan to disseminate the results of your work. This may involve more than publication in a respected journal. Your plan should encompass, where appropriate, a considered follow-through into training programmes of other professionals and presentations to service users.

The Research Department can advise on dissemination of outcomes.

Section 13: Strategy for taking the work forward if the research project is productive

If your research project is productive, what will your strategy be for taking this forward? Will you be undertaking further research based on the results? Do you intend to apply to funding bodies for continuation of support?

Section 14: Intellectual Property arrangements

The NHS Executive has adopted a policy framework for the management of intellectual property within the NHS arising from R&D funded from the R&D Levy. A Health Service Circular (HSC 1998/106: Property Framework for the Management of Intellectual Property within the NHS arising from Research & Development) sets out this framework, which will help to ensure that intellectual property derived from NHS R&D is owned and exploited in the best interests of the NHS and the country as a whole, by those best able to do so. It is intended to remove current uncertainties about roles and responsibilities.

Section 15: Costing the project

When costing your application, be sure you have included everything you will need. Accurate identification and costing, can be difficult for less experienced researchers. For example: transcription of interviews or data analysis take much longer than you might realise - for every hour of interview you should expect to have to allow 4-5 hours of transcription time. The Finance Department and the Research Department can advise on the costing process.

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Irrespective of whether there is **funding** associated with the project, all costs should be identified accurately. These should include direct research costs (salaries and consumables – see below) as well as the use of clinical resources both for the host directorate and for support services. These need to be agreed with the clinical director/general manager in the location where the research is taking place and, where applicable, with the manager providing the support service.

- **Staff costs:** for each additional staff member requested the following information is required
 - a. A description of the type and grade of staff required
 - b. The proportion of a whole-time equivalent (WTE) required and an indication of which months of the project the appointment will cover (e.g. 0.5 WTE for months 2-8), and the assumed start date
 - c. Basic Pay, National Insurance, and Employers' Superannuation - all identified separately
 - d. All costs should be quoted at pay levels in force at the time of application. Please indicate the effective date of the last pay award to be settled for the grade of staff to be appointed, and whether there is a further award pending. Costs need to take account of pay and price levels for the duration of the project, reflecting any outstanding pay awards
 - e. Where staff are to be employed on an incremental scale this should be reflected in the costings.

- Other recurrent expenses: these include maintenance costs for equipment outside the guarantee period and running costs (e.g. stationery, postage, laboratory consumables, audio tapes, telephone and travelling expenses etc) proper to the project.
- Equipment: it is expected that the applicant's department will provide basic equipment. For new equipment all prices should be quoted gross, including VAT where applicable.
- Other non-recurrent expenses: this includes items like, one-off fees for advice/consultancy, the costs of presenting the results of the research at conferences, or submitting them for publication.

Note: The Trust or University will engage Staff working on research projects, in accordance with its establishment practice.

Justification for resources requested

Where you are applying for funding from a local charity or departmental resource, you need to explain why you need the staff/items for which you are requesting funding. It is not enough just to list what is requested. For example, if you are requesting staff costs, explain why the project needs that particular type of staff, and why the grade quoted is the appropriate one. In the case of equipment, are you sure that there is no existing equipment which you can use - a very good case would be needed for basic items which should already be available in your department. R&D funds are not normally used to fund standard office equipment or standard computer hardware and software.

In general R&D funds are not used to fund additional sessions for people already in full-time employment, paid by the NHS or by a University unless it can be shown that the money will pay another individual to carry out some of that person's normal duties (locum costs), thus releasing them to do R&D work.

If salaries are requested, establish the conditions of the funding body as to whether you need to include allowances for pay awards. Always include any increments due during the course of the project. You should indicate effective date of latest settled pay award.

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Section 16: Funding source

The potential funding source needs to be clearly stated: e.g. charitable account.

Section 17: References

References in support of the protocol: these should give the full journal reference.

Section 18: Abstract

Include a brief abstract outlining the key issues contained in your protocol. It should be readable by a professional non-specialist in your research area.

Section 19: Curriculum Vitae

Please include a brief CV, including a list of any current grants and your publications during the last five years.

Section 20: Statistical opinion

Where applicable, append evidence of a favourable statistical opinion.

Appendix

REPORTING ADVERSE EVENTS

INTRODUCTION

An adverse incident is any incident, occurrence or accident that results in an injury or illness to a patient visitor or member of staff. Normally, all such incidents must be reported on the RMGC.

1. PROCEDURE FOR EVENTS DURING A CLINICAL TRIAL OF A MEDICINAL PRODUCT

Definitions (EU Directive 2001/20/EC)

Adverse event

Any untoward medical occurrence in a patient or clinical trial subject administered a medicinal product and which does not necessarily have a causal relationship with this treatment.

Adverse reaction

An untoward and unintended response to an investigational medicinal product related to any dose administered.

Unexpected adverse reaction

An adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g. the investigators brochure for an unauthorised investigational product or summary of product characteristics for an authorised product).

Serious adverse event or reaction

An adverse event or reaction that results in death, is life threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect.

Reporting of Serious Adverse Events

The Ethics Committees **and**, as soon as possible after the event, the **RMGU Office** should be notified of

- all **unexpected** serious adverse events or reactions occurring in patients recruited at the PCTs.
 - any **unexpected increase** in the incidence of expected serious adverse events or reactions. Investigators must have a mechanism in place to monitor this.
- a. An **adverse incident** form should be completed, making clear that the incident refers to a research project, and sent to the Risk Manager as well as the R&D Manager.
 - b. Reporting such events is in the interests of the research subject, the researcher and PCT. The Trust carries full legal liability for any claims of negligence where an NHS employee fails to deal adequately with an adverse drug reaction.
 - c. Reporting is a requirement whenever approval is given by the Ethics Committee for a research study to proceed, and this will also be stated on the Ethics Committee application form.

Appendix

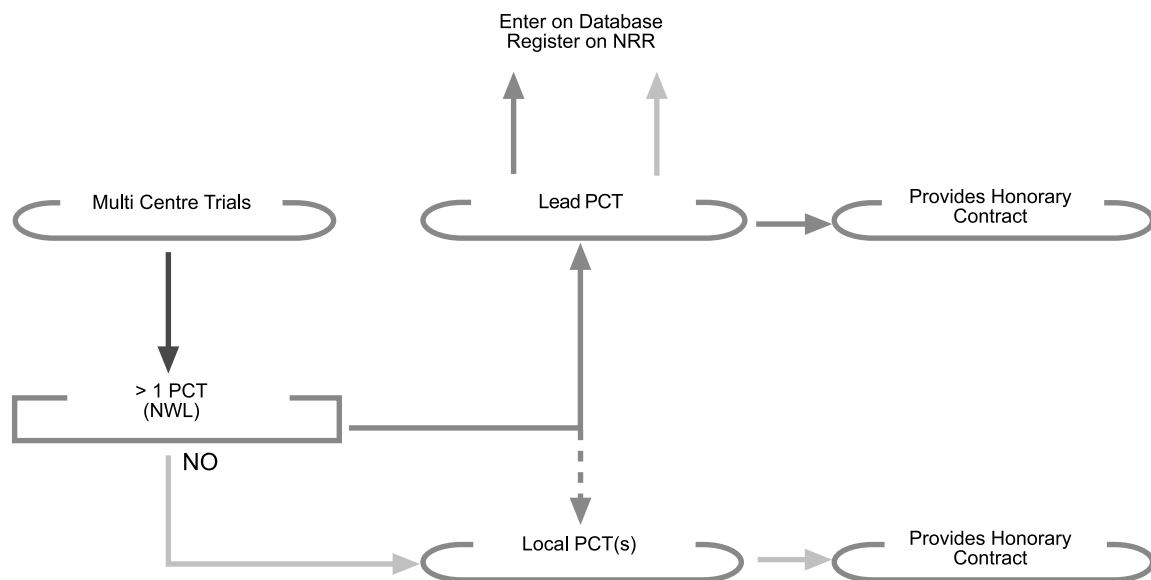
- d. It is **not** necessary to report:
- Serious adverse reactions or events that are consistent with the established toxicity of the study medication. This is because this will already be described in the patient information leaflet and taken into account in the research protocol.
 - Adverse events related to expected disease progression, existing medical conditions, or unrelated to the trial protocol.
- f. However, the Investigators Brochure usually states that all serious adverse events should be routinely reported to the study Sponsor.
- g. The following steps should be taken:
- The sponsor of the trial should be informed in accordance with the investigator's contractual obligations. The sponsor has legal reporting requirements under the Medicines Act and EC law.
 - The researcher or principal researcher should inform the Chair or Vice-Chair of the Ethics Committee that dealt with the original application as soon as possible after the incident occurs.
- h. The Chair or Vice-Chair of the research ethics committee will decide if the investigator should stop recruitment pending investigation, and whether the opinion of an independent expert should be sought.
- i. The adverse event or reaction will be considered at the next Ethics Committee meeting and a decision will be made on the need to change the trial protocol and/or patient information leaflet.

2. PROCEDURES FOR RESEARCH PROJECTS THAT ARE NOT CLINICAL TRIALS

Unexpected adverse events or reactions that occur during a research project that is not a clinical trial should also be reported to the Local Ethics Committee that dealt with the original application. Reporting is a requirement whenever approval is given by the Ethics Committee for a research study to proceed, and this is stated on the Ethics Committee application form.

Appendix

Processing Multi-Centre Trials



Please Note

All Multi-Centre Projects must have an LREC Approval
Any LREC within the NWL will cover any NWL PCT
Responsibility of LREC Approval remains with the Researcher(s)

Appendix

International Conference on Harmonisation/ Good Clinical Practice

- Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP and the applicable regulatory requirement(s).
- Before a trial is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual trial subject and society. A trial should be initiated and continued only if the anticipated benefits justify the risks.
- The rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society.
- The available non clinical and clinical information on an investigational product should be adequate to support the proposed clinical trial.
- Clinical trials should be scientifically sound, and described in a clear, detailed protocol.
- A trial should be conducted in compliance with the protocol that has received prior institutional review board (IRB)/independent ethics committee (IEC) approval/favourable opinion.
- The medical care given to, and medical decisions made on behalf of, subjects should always be the responsibility of a qualified physician or, when appropriate, of a qualified dentist.
- Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).
- Freely given informed consent should be obtained from every subject prior to clinical trial participation.
- All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.
- The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).
- Investigational products should be manufactured, handled, and stored in accordance with applicable good manufacturing practice (GMP). They should be used in accordance with the approved protocol.
- Systems with procedures that assure the quality of every aspect of the trial should be implemented.

Appendix

Process for Obtaining PCT Approval for Research Projects

Staff wishing to undertake research, ranging from small scale research to support dissertations and projects through to involvement in large scale multi centre trials, must register their research with the PCT. To do this, the following process must be followed.

For local research

Application includes **all** of the following:

1. research protocol synopsis
2. a copy of the approval letter from MREC/ LREC.
3. a completed application form, confirming that the researcher understands their roles and responsibilities in respect of:
 - the data Protection Act
 - Health and Safety
 - patient consent
 - appropriate recording of information in patients notes
 - reporting complaints and adverse incidents
 - having been appropriately trained and inducted in study methodology
4. a copy of the letter from the practice to the study sponsor indicating that the practice is willing to be involved.
5. a copy of the signed indemnity form (if applicable)

Where there is no local researcher, complete the standard research governance application form, ticking the box indicating “No local researcher”. No further information is required, although a copy of the MREC approval letter, if available, is helpful.

Then:

- copy to Research Governance Manager
- RMGU will log in Research Database
- then Director of RMGU will review or delegate the task

Assuming that all information is completed, authorisation will be provided within 10 working days of receipt of the application (appendix 4 – for local research, appendix 5 for where there is no local researcher)

The researcher/study group is expected to submit an annual update on progress to the PCT. This can be a copy of the form submitted to MREC/LREC.

Appendix

Specimen Letter – from the Practice to the Study Coordinator

Practices participating in research are asked to formally write to the Chief Investigator confirming that the practice will participate in the research. This letter should be included in the research application to the PCT. A specimen letter is given below.

(Name and address of Chief Investigator)

Dear (Chief Investigator)
(Name of the research study)

I am pleased to confirm that (General Practice name) will take part in the (name of the research study) and will work with you to ensure that the study is conducted according to the agreed protocol and in compliance with the legal requirements and the three key indicators from the Research Governance Framework for Health and Social Care. I also confirm that I have the authority to commit the practice to participation in the study.

Specifically I can confirm that:

- the main contact for the study will be (name of main contact if not letter signatory)
- the practice has received the study protocol and letter(s) of approval from the Research Ethics Committee(s)
- the practice staff who will be involved in the study are (names and designation of all staff involved) and you will be informed if any of them change.
- all the above staff have received appropriate training in the aspects of the study protocol to the work they will be conducting for you in the study including collecting informed receive further training as necessary or as indicated in the protocol
- all the above staff will abide by the study protocol
- all informed consent forms for the study will be sent to you, with copies retained in the patients' records
- I have advised Brent PCT that the practice is participating in the study
- the practice is compliant with its legal requirements in respect of the Data Protection Act, the Health and Safety Act and financial probity.

I understand that if there are any changes to the study protocol that these will be notified to the Local Research Ethics Committee and that you will advise of these by way of an amended protocol and approval letter and arrange any further training necessary.

Yours sincerely,

Appendix

Specimen PCT Research Governance Approval Authorisation Letter for Local Research

Ref:

Date

Dear Chief Investigator

Re:

Further to your letter dated xxxxx, I am pleased to confirm that this PCT has approved your research application.

The project must be started within 6 months of this approval being given. Failure to do this will require a second submission. The conditions of approval are as laid out below.

- Appropriate indemnity arrangements must be in place.
- The documents approved are those approved in the MREC/LREC submission.
- You must follow the protocol agreed, and any changes to the protocol will require further review by MREC/LREC, and a further application to this PCT.
- You must regularly audit the process and outcome of gaining informed consent to participate in a trial and send copies of reports to the PCT upon request.
- You must promptly inform us of:
 1. deviations from or changes to the protocol which are made to eliminate immediate hazards to the research participants.
 2. any changes that increase the risk to participants and/or significantly affect the conduct of the research.
 3. all adverse drug reactions that are both serious and unexpected.
 4. new information that may affect adversely the safety of the participants or the conduct of the trial.

Please note that you will be expected to return similar information to MREC/LREC, but this information must also be copied into PCT systems, particularly those for managing risk.

You must return a short progress report form to us one year from the date of this letter and thereafter on an annual basis. This can be a copy of the forms submitted to MREC/LREC.

Yours sincerely,

Appendix

Specimen PCT Research Governance Approval Authorisation Letter where there is no Local Researcher

Ref:
Date

Dear XXX

Re:

Further to your application for research governance approval dated xxxxx, I am pleased to note your participation in this work stream. As this is work in which there is forwarding of information only, with no direct patient contact, then this PCT will require no further information from you in connection with it. Please note however, that if patient contact develops, or a formal trial commences, you will need to apply for Research Ethical Approval and PCT research governance approval.

Yours sincerely,

Indemnity Form

To Be Completed by Supervisors From Universities or Other Non-Commercial Agencies

INDEMNITY

I can confirm that _____
Is a student of _____
And that I am his/her Supervisor for this project.

I can confirm that _____ (Name of university etc.)
will indemnify the Trust and the researcher against all actions and litigations that may arise from the
execution of this research within the Primary Care Trust.

NAME _____
STATUS _____
SIGNATURE _____
DATE _____