



RESEARCH RESOURCE PACK

LAW, GOVERNANCE, AND BEST PRACTICE

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WELCOME AND INTRODUCTION

Welcome and Introduction

Welcome to *the* legal resource on research governance and the key legal rules associated with it. This document will:

tell you what you need to know;

tell you what the law has to say;

give you practical examples of application; and

point you in the right direction of resources and places of further help and support.

Research in the NHS requires all involved to understand their roles and responsibilities. This applies to you, to the participants in the research and the numerous other stakeholders with whom you will have contact. This can be a legal obligation as well as a requirement of the NHS.

High quality research should always be based on sound scientific, ethical and legal principles. This ensures that risk to participants, clinicians and the NHS is minimised. In normal clinical practice we all strive to provide a better standard of care for patients. This same guiding principle should be applied to the research being carried out and the participants in that research.

The governance of research in the NHS and the law surrounding it is set out in a jigsaw of various documents and legislation and we have pieced the jigsaw together into a helpful 'one stop shop' format.

Because we know that not every reader of this legal resource pack will need the same level of detail, each section is divided into easily digestible chunks with a 'key points' summary before moving onto a more detailed analysis of the topics. For those of you wanting more detail on any given topic, we have set out links and suggestions for further reading and information.

It is likely that, if you have any queries about a particular topic, someone will have encountered that problem or query before. The 'Further Guidance' section of this pack gives details of all of the key organisations who can assist. However, your first port of call should be PCRN.



About PCRN-EMSY

The PCRN is a nationwide initiative which aims to improve the speed, quality, and integration of research in primary care ultimately resulting in improvements in screening, prevention, early diagnosis, treatment and care for patients.

The PCRN across the East Midlands and South Yorkshire

The Primary Care Research Network- East Midlands and South Yorkshire (PCRN-EMSY) is hosted by NHS Leicester City and managed by Louise Woodward. The Clinical Lead is Professor Andrew Wilson. Andrew is a GP in a research active practice and Professor of Primary Care Research in the Department of Health Sciences at University of Leicester.

PCRN-EMSY builds on long-standing collaborations between NHS researchers, research managers, Trent Research Design Service (RDS), and academic departments of primary care and related disciplines in eight universities. The network promotes and supports the delivery of high quality research in primary care. The network's coordinating centre is in Leicester and includes the Network Manager, an Office Manager and a Portfolio Officer. The network has three hubs, each led by a Locality Manager:

LNR (Leicestershire, Northamptonshire and Rutland): Janice Strand
Trent (Derbyshire, Nottinghamshire and Lincolnshire): Nathalie Bailey-Flitter
South Yorkshire (Barnsley, Doncaster, Rotherham and Sheffield): Michelle Horspool

Research Studies

PCRN-EMSY is assembling a balanced portfolio of local and national studies, commercial (industry-led) and non-commercial (i.e. academic or NHS studies) which employ a range of methodologies. Partners are currently participating in academic, commercial and collaborative research at a local, national and international level.

Contact us

Visit our website for details: www.pcrn-emsy.org.uk



About Browne Jacobson LLP

Browne Jacobson LLP is a law firm which specialises in, amongst other things, health law. Based in Nottingham, Birmingham and London, we provide coverage on all key legal issues, particularly to our NHS clients.

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RESEARCH GOVERNANCE

General Overview

The Research Governance Framework for Health and Social Care was first published in 2001 in response to the widely reported and high profile scandals of Bristol and Alderhey. The second edition was published in 2005 (the "Framework") to take account of new legislative requirements.

The Framework can be found here:

http://www.dh.gov.uk/en/Researchanddevelopment/A-Z/Researchgovernance/DH_4002112



*Research Governance
Framework
for
Health and Social Care*

Second edition, 2005

The Secretary of State for Health was quoted as saying in 2001:

"... patients will no longer accept the rather traditional, paternalistic attitude of the NHS that the benefits of medicine, science or research are self-evident, regardless of the wishes of patients or their families - frankly that has to change. The days are gone when the NHS can act as a secret society"

The Framework was introduced to standardise research practices across health and social care sector, to promote improvements in research quality and to safeguard the public. The Framework has five domains: ethics, science, information, health & safety, and finance and intellectual property. It sets monitoring and assessment standards and defines mechanisms to deliver those standards.

Research Governance (RG) and the Framework applies to all research under the ambit of the Secretary of State for Health and includes clinical and non-clinical research. RG is not optional and must be complied with in order to satisfy the statutory 'duty of quality' imposed by Section 45 of the Health and Social Care (Community Health Standards) Act 2003. Further, the Framework notes that the rules that it sets apply to:

"...research concerned with the protection and promotion of public health, research undertaken in or by the Department of Health, its non-Departmental Public Bodies and the NHS, and research undertaken by or within social care agencies. It includes clinical and nonclinical research; research undertaken by NHS or social care staff using the resources of health and social care organisations; and any research undertaken by industry, charities, research councils and universities within the health and social care systems that might have an impact on the quality of those services".

We'll cover much of the content of the Framework in the course of this Legal Resource Pack but it is worth noting that all of the organisations and individuals noted in the quotation above are expected to be able to demonstrate adherence to the Framework.

The proper governance of research ensures that safe systems of care are in place when research is being undertaken, and is now a core duty of all NHS Trusts. NHS Organisations are assessed for compliance by the Healthcare Commission (soon to become part of the Care Quality Commission) under standard C12 of the Department of Health's *Standards for Better Health*.

Key Points

In addition to a number of areas of the Framework covered in the remainder of this Legal Resource Pack, section 3 of the Framework sets out a comprehensive 'A to Z' of those people who would normally be involved in research (of the types noted in the quotation above) together with details of the responsibilities of each of those people and their lines of accountability in respect of their performance of those responsibilities.

Those involved include the:

Name of person involved in research	Responsibility
Chief Investigator	The person who takes overall responsibility for the design, conduct and reporting of a study if it is at one site; or if the study involves researchers at more than one site, the person who takes primary responsibility for the design, conduct and reporting of the study, whether or not that person is an investigator at any particular site.
Employing Organisation	Organisation employing the chief investigator, investigators or other researchers. Employers remain liable for the work of their employees. The organisation employing the chief investigator normally holds the contract or grant agreement with the funder of the study. Organisations holding contracts with funders remain responsible for the management of the funds provided.
Funder	Organisation providing funding for a study (through contracts, grants or donations to an authorised member of the employing and/or care organisation). The main funder typically has a key role in scientific quality assurance. In any case, it remains responsible for securing value for money.
Investigator	Person responsible, individually or as leader of the researchers at a site, for the conduct of a study at that site. For clinical trials involving medicines, an investigator must be an authorised health professional.
Organisation Providing Care	Organisation responsible for providing health or social care to patients and/or service users and carers participating in a study. Health and social care organisations remain liable for the quality of care, and for their duty towards anyone who might be harmed by a study.

Participant	Patient, service user, carer, relative of the deceased, professional carer, other employee, or member of the public, who consents to take part in a study. (In law, participants in clinical trials involving medicines are known as subjects.)
Principal Investigator	The leader responsible for a team of individuals conducting a study at a site.
Researchers	Those conducting the study.
Research Ethics Committee	Committee established to provide participants, researchers, funders, sponsors, employers, care organisations and professionals with an independent opinion on the extent to which proposals for a study comply with recognised ethical standards. For clinical trials involving medicines, the ethics committee must be one recognised by the United Kingdom Ethics Committee Authority.
Responsible Care Professional	Doctor, nurse, social worker or other practitioner formally responsible for the care of participants while they are taking part in the study.
Sponsor	Individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a study. (A group of individuals and/or organisations may take on sponsorship responsibilities and distribute them by agreement among the members of the group, provided that, collectively, they make arrangements to allocate all the responsibilities in this research governance framework that are relevant to the study.)

Section 3 of the Framework also provides a very useful 'Frequently Asked Questions' section on the specific responsibilities of these key people involved in research together with answers to those questions.

CONSENT FOR RESEARCH PURPOSES

General Overview

Research that is scientifically, ethically and legally sound enhances the welfare of society and its members. It is essential to the promotion and protection of health and to modern health services as it forms the basis of evidence-based health care. Research is also necessary for example, to establish the safety and efficacy of new drugs, therapies or techniques. Poorly conducted research however, can cause real distress when it goes wrong. Proper management of research practice is essential to ensure that the public can have confidence in, and benefit from, quality research in health and social care¹.

The notion of 'informed consent' is central to the ethics of modern research and forms the basis of protection for research subjects. According to De Cruz (2002)², the requirement for consent has several functions: first to promote individual autonomy; and secondly to encourage rational decision-making, both of which derive from the basic right to self-determination, which has been re-affirmed by the English Courts.

If a valid consent is not obtained then:

- A trespass to the person i.e. a 'battery'³ may be committed
- If injury [to the participant] results, this may constitute a criminal offence
- An action of negligence can result from inadequate information being provided to the participant

Although it is rarely a legal requirement to seek written consent⁴, it is good practice to do so in certain circumstances⁵ and [for the purposes of this document], this includes research.

Furthermore, the fundamental W.H.O document outlining good practice in research (Declaration of Helsinki (1964)⁶) espoused that written consent was always preferable;

"...obtain the subject's freely given informed consent, preferably in writing. If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed".

In addition, The Nuffield Council on Bioethics Working Party: Ethical & Legal Issues *state that consent must be explicit and all relevant information disclosed.*

Essentially, the purpose of a consent form is to record what has been agreed between the researcher and participant. Consequently, the consent form cannot protect participants from harm, except to the extent that it discloses information, which may lead to a prospective participant choosing whether or not to take part in the research.

¹ DH (2005) Research Governance Framework for Health & Social Care (Second Edition), Department of Health, London.

² De Cruz.P (2002) Nutshells: Medical Law (First Edition), Sweet & Maxwell, London.

³ A battery takes place when there is a non-consensual touching. There is no legal requirement to prove that the touching was hostile.

⁴ The Mental Health Act 1983 and the Human Fertilisation and Embryology Act 1990 require written consent in certain circumstances. The EU Directive on Clinical Trials mandates it.

⁵ Circumstances other than research are not discussed herein.

⁶ World Medical Association (1964) Ethical Principles for Medical Research Involving Human Subjects (Declaration of Helsinki).

The Risks

By failing to gain written consent from participants, researchers are exposing themselves to a number of potential risks;

- Complaints arising from research participants: without a properly completed written consent form, it may be difficult to prove 'beyond reasonable doubt' that consent was obtained.
- In light of the above, it is difficult to establish what was or wasn't consented to (i.e. using information for research purposes, as opposed to believing the intervention was part of 'usual care').
- A poorly managed consent procedure may lead others (including sponsors and funders) to question the integrity of the research data/findings (e.g. fabricated data).
- Recognised scientific journals would normally expect written consent to have been obtained from all study participants and may, therefore, refuse to publish.
- Unless the rationale for not obtaining written consent was explained, justified, and agreed by both the REC and R & D Departments prior to study commencement, then the researcher is also likely to be in breach of their approval conditions.

The Framework and Consent

The Research Governance Framework (see earlier in this Legal Resource Pack) highlights the fact that consent from participants in research studies is vital:

"Informed consent is at the heart of ethical research. Most studies involving individuals must have appropriate arrangements for obtaining consent, and the ethics review process pays particular attention to those arrangements".

Ultimately, as noted by the GMC in its 2002 publication, *Research: The Role and Responsibilities of Doctors*, "partnership between participants and the health care team is essential to good research practice and such partnerships are based on trust". GMC Research Guidance Can be found at:

http://www.gmc-uk.org/guidance/ethical_guidance/5991.asp

Such organisations must start with the health care and/or the relevant researchers being up front with the participant as to what they would like to use the participant's personal information and or tissue etc and to obtain the relevant consents for such uses.

There are a number of strands for ensuring that this consent is 'informed'. These strands are not all contained in one statute. So we'll look at the various pieces of legislation that may be relevant for researchers below.

The Data Protection Act 1998 and Consent

The Basic Rules under the DPA

The Data Protection Act 1998 (the "DPA") is the overarching legislation when it comes to consent to use of personal information in research. The DPA provides that any organisation or person who processes (holds, uses, discloses or does any action with) personal information (anything which identifies a living individual and which affects the privacy of that individual) must do so in accordance with the strict rules set out in the DPA.

These strict rules are summarised in Schedule 1 of the DPA and are known as the 'Data Protection Principles':

- 1 Personal information must be processed fairly and lawfully and, in particular, shall not be processed unless - (a) at least one of a set of conditions (Schedule 2 of the DPA) is met and (b) in the case of 'sensitive personal data' (which definition includes personal information relating to the physical and mental health of an individual), at least one of a further set of conditions (Schedule 3 of the DPA) is also met.
- 2 Personal information must be obtained only for one or more specified and lawful purposes, and shall not be further processed in any manner incompatible with that purpose or those purposes.
- 3 Personal information must be adequate, relevant and not excessive in relation to the purpose or purposes for which they are processed.
- 4 Personal information must be accurate and, when necessary, kept up to date.
- 5 Personal information processed for any purpose or purposes must not be kept for longer than is necessary for that purpose or those purposes.
- 6 Personal information must be processed in accordance with the rights of data subjects under the DPA.
- 7 Appropriate technical and organisational measures must be taken against unauthorised or unlawful processing of personal information and against accidental loss or destruction of, or damage to, personal information.
- 8 Personal information must not be transferred to a country or territory outside the European Economic Area unless that country or territory ensures an adequate level of protection for the rights and freedoms of data subjects in relation to the processing of personal data.

The key Data Protection Principle is the first principle - 'fair and lawful processing' of personal information. As noted above, researchers will need to carefully consider the conditions required in Schedules 2 and 3 of the DPA in order to ensure that their use of personal and sensitive personal information in relation to the research being undertaken is fair and lawful.

In each of Schedule 2 and Schedule 3 of the DPA, the only conditions likely to be engaged in allowing researchers to process the personal information of participants are 'condition 1' of Schedule 2 (the data subject has consented to the processing of the personal information) and 'condition 1' of Schedule 3 (the data subject has given *explicit* consent to the processing of the sensitive personal information - in this case, the health information).

'Consent'

Whilst there is other legislation which impacts upon capacity to give consent (more on this below), the DPA deals with consent to processing of personal data in relatively general terms. It provides that consent to the processing must be "informed" and freely given.

To be informed and freely given, the participants must fully understand exactly what participation in the study will mean for them and the use of their personal information.

In practical terms, the GMC has noted (in its 2002 publication, *Research: The Role and Responsibilities of Doctors*) that effective communication is the key to enabling participants to make informed decisions:

"When providing information you must do your best to find out about participants' individual needs and priorities. For example, participants' current understanding of their condition and treatment, beliefs, culture, occupation or other factors may have a bearing on the information they require. You must not make

assumptions about participants' views, but discuss matters with them, and ask whether they have any concerns about the treatment or the risks involved in the research programme.

You must ensure that any individuals whom you invite to take part in research are given the information which they want or ought to know, and that is presented in terms and a form that they can understand. You must bear in mind that it may be difficult for participants to identify and assess the risks involved. Giving the information will usually include an initial discussion supported by a leaflet or sound recording, where possible taking into account any particular communication or language needs of the participants. You must give participants an opportunity to ask questions and to express any concerns they may have.

The information provided should include:

- what the research aims to achieve, an outline of the research method, and confirmation that a research ethics committee has approved the project;*
- the legal rights and safeguards provided for participants;*
- the reasons that the patient or volunteer has been asked to participate;*
- if the project involves randomisation, the nature of the process and reasons for it, and the fact that in double-blind research trials neither the patient nor the treatment team will know whether the patient is receiving the treatment being tested or is in the control group;*
- information about possible benefits and risks;*
- an explanation of which parts of the treatment are experimental or not fully tested;*
- advice that they can withdraw at any time and, where relevant, an assurance that this will not adversely affect their relationship with those providing care;*
- an explanation of how personal information will be stored, transmitted and published; · what information will be available to the participant about the outcome of the research, and how that information will be presented;*
- arrangements for responding to adverse events;*
- details of compensation available should participants suffer harm as a result of their participation in the research.*

You must allow people sufficient time to reflect on the implications of participating in the study, and provide any further information they request, including a copy of the protocol approved by the research ethics committee. You must not put pressure on anyone to take part in the research. You should make a record of the discussion and the outcome."

GMC Research Guidance Can be found at:

http://www.gmc-uk.org/guidance/ethical_guidance/5991.asp

Section 33 of the DPA and Consent

There has been some debate in the last few years as to why the Research Governance Framework has not referenced section 33 of the DPA. This provides that:

"For the purposes of the second data protection principle, the further processing of personal data only for research purposes in compliance with the relevant conditions is not to be regarded as incompatible with the purposes for which they were obtained."

Section 33 of the DPA goes on to say that:

"In this section "research purposes" includes statistical or historical purposes and "the relevant conditions", in relation to any processing of personal data, means the conditions: (a) that the data are not processed to support measures or decisions with respect to particular individuals, and (b) that the data are not processed in such a way that substantial damage or substantial distress is, or is likely to be, caused to any data subject".

So, on the face of it, section 33 of the DPA does allow the processing of personal information for research purposes provided that that information is not used by the researchers in a way which will 'support measures' in respect of the data subject in question or cause the data subject in question substantial damage and/or distress.

It seems likely that the Framework does not sanction reliance upon section 33 for two reasons:

- whilst clearly a non-exhaustive list, the DPA defines (at section 33 - as noted in the quotation above) 'research purposes' quite narrowly - *"'research purposes' includes statistical or historical purposes"*. It is arguable that any further research purposes would need to be interpreted as being within a class of purposes limited to things very similar to statistical or historical purposes; and
- the very spirit engendered by the DPA and the requirement of openness between researchers and participants is such that it is not acceptable to allow researchers to make value judgments as to when consent can be waived. This is particularly the case given that research ethics committees would need to be made aware of this 'waiver' of consent.

The Medicines For Human Use (Clinical Trials) Regulations 2004 and Consent

The Medicines For Human Use (Clinical Trials) Regulations 2004 (as amended) (the "2004 Regulations") set out specific conditions and principles which apply to informed consent, and to the recruitment of minors and incapacitated adults to participate in a clinical trial of investigational medical products (with that type of clinical trial often being referred to as 'CTIMPs').

The 2004 Regulations transpose into English law the European Clinical Trials Directive. The 2004 Regulations provide that:

"A person gives informed consent to take part in a clinical trial only if his decision: (a) is given freely after that person is informed of the nature, significance, implications and risks of the trial; and (b) either: (i) is evidenced in writing, dated and signed, or otherwise marked, by that person so as to indicate his consent, or (ii) if the person is unable to sign or to mark a document so as to indicate his consent, is given orally in the presence of at least one witness and recorded in writing".

The same definition applies to the giving of informed consent by a person with parental responsibility, or a legal representative, on behalf of the trial subject.

The 2004 Regulations go on to set out the specific conditions that apply to the giving of informed consent by:

- a capable adult;
- minors;
- incapacitated adults.

The 2004 Regulations also specify the responsibilities of ethics committees in trials involving minors or incapacitated adults.

The National Research Ethics Service and National Patient Safety Agency has published an excellent in-depth guide to the 2004 Regulations and the practical steps that must be followed in each case to obtain informed

consent in CTIMPs. This guide can be found at: <http://nres.npsa.nhs.uk/applications/guidance/consent-guidance-and-forms/?entryid62=66934>

Section 251 of the National Health Service Act 2006 and Consent

Section 251(1) of the National Health Service Act 2006 provides that, notwithstanding section 30 of the Mental Capacity Act 2005 (more on this below):

"The Secretary of State may by regulations make such provision for and in connection with requiring or regulating the processing of prescribed patient information for medical purposes as he considers necessary or expedient in the interests of improving patient care, or (b) in the public interest".

The powers set out above are exercised through the Health Service (Control of Patient Information) Regulations 2002 (as amended) which provide, amongst other things, that certain patient information may be used for research purposes without consent (and such usage would not be in breach of the common law of confidence). These Regulations provide that such usage must be approved by the Research Ethics Committee and that the usage is restricted to the following circumstances:

- the processing of confidential patient information for medical purposes with a view to making the patient in question less readily identifiable from that information.
- the processing of confidential patient information that relates to the present or past geographical locations of patients (including where necessary information from which patients may be identified) which is required for medical research into the locations at which disease or other medical conditions may occur.
- the processing of confidential patient information to enable the lawful holder of that information to identify and contact patients for the purpose of obtaining consent: (a) to participate in medical research; (b) to use the information for the purposes of medical research, or (c) to allow the use of tissue or other samples for medical purposes.
- the processing of confidential patient information for medical purposes from more than one source with a view to: (a) linking information from more than one of those sources; (b) validating the quality or completeness of: (i) confidential patient information, or (ii) data derived from such information;
- avoiding the impairment of the quality of data derived from confidential patient information by incorrect linkage or the unintentional inclusion of the same information more than once.
- the audit, monitoring and analysing of the provision made by the health service for patient care and treatment.
- the granting of access to confidential patient information for one or more of the above purposes.

The Mental Capacity Act 2005 and Consent

The Mental Capacity Act 2005 (the "MCA") came into force in 2007. It provides safeguards for a person who lacks capacity to consent to research. Researchers have to respect the person's previous wishes, and have to consult someone, such as a carer, who is able to take an independent view of the incapacitated person's interests, wishes and feelings.

There is a legal requirement for review of the proposed inclusion of someone who lacks capacity in a study by a research ethics committee and for researchers to follow the Mental Capacity Act Code of Practice.

Anyone assessing someone's capacity to make a decision for themselves should use the two-stage test of capacity:

- Does the person have an impairment of the mind or brain, or is there some sort of disturbance affecting the way their mind or brain works? (It doesn't matter whether the impairment or disturbance is temporary or permanent.)
- If so, does that impairment or disturbance mean that the person is unable to make the decision in question at the time it needs to be made?

The law under the MCA is very specific as to when researchers can and can't ask persons lacking capacity to take part in research. It is therefore worth reproducing the legislation. It is worth noting, however, that there is a very useful statutory 'Mental Capacity Act Code of Practice' which must be adhered to and which gives practical guidance on all of the issues raised under the MCA. The Code of practice can be found at:

<http://www.dca.gov.uk/menincap/legis.htm#codeofpractice>

In addition, the NHS Research and Development Forum has set out a very useful guide as to when the MCA doesn't apply. This can be found here:

www.rdforum.nhs.uk/docs/mca_guidance.doc .

Section 30 of the MCA provides, amongst other things, that:

- (1) *Intrusive research carried out on, or in relation to, a person who lacks capacity to consent to it is unlawful unless it is carried out: (a) as part of a research project which is for the time being approved by the appropriate body for the purposes of this Act in accordance with section 31, and (b) in accordance with sections 32 and 33.*
- (2) *Research is intrusive if it is of a kind that would be unlawful if it was carried out (a) on or in relation to a person who had capacity to consent to it, but (b) without his consent.*
- (3) *A clinical trial which is subject to the provisions of clinical trials regulations is not to be treated as research for the purposes of this section.*
- (4) *"Appropriate body", in relation to a research project, means the person, committee or other body specified in regulations made by the appropriate authority as the appropriate body in relation to a project of the kind in question.*
- (5) *"Clinical trials regulations" means: (a) the Medicines for Human Use (Clinical Trials) Regulations 2004 and any other regulations replacing those regulations or amending them, and (b) any other regulations relating to clinical trials and designated by the Secretary of State as clinical trials regulations for the purposes of this section.*

Section 31 of the MCA provides that:

- (1) *The appropriate body may not approve a research project for the purposes of this Act unless satisfied that the following requirements will be met in relation to research carried out as part of the project on, or in relation to, a person who lacks capacity to consent to taking part in the project ("P").*
- (2) *The research must be connected with: (a) an impairing condition affecting P, or (b) its treatment.*

- (3) *"Impairing condition" means a condition which is (or may be) attributable to, or which causes or contributes to (or may cause or contribute to), the impairment of, or disturbance in the functioning of, the mind or brain.*
- (4) *There must be reasonable grounds for believing that research of comparable effectiveness cannot be carried out if the project has to be confined to, or relate only to, persons who have capacity to consent to taking part in it.*
- (5) *The research must: (a) have the potential to benefit P without imposing on P a burden that is disproportionate to the potential benefit to P, or (b) be intended to provide knowledge of the causes or treatment of, or of the care of persons affected by, the same or a similar condition.*
- (6) *If the research falls within paragraph (b) of subsection (5) but not within paragraph (a), there must be reasonable grounds for believing: (a) that the risk to P from taking part in the project is likely to be negligible, and (b) that anything done to, or in relation to, P will not: (i) interfere with P's freedom of action or privacy in a significant way, or (ii) be unduly invasive or restrictive.*
- (7) *There must be reasonable arrangements in place for ensuring that the requirements of sections 32 and 33 will be met.*

Section 32 of the MCA provides that:

- (1) *This section applies if a person ("R"): (a) is conducting an approved research project, and (b) wishes to carry out research, as part of the project, on or in relation to a person ("P") who lacks capacity to consent to taking part in the project.*
- (2) *R must take reasonable steps to identify a person who: (a) otherwise than in a professional capacity or for remuneration, is engaged in caring for P or is interested in P's welfare, and (b) is prepared to be consulted by R under this section.*
- (3) *If R is unable to identify such a person he must, in accordance with guidance issued by the appropriate authority, nominate a person who: (a) is prepared to be consulted by R under this section, but (b) has no connection with the project.*
- (4) *R must provide the person identified under subsection (2), or nominated under subsection (3), with information about the project and ask him: (a) for advice as to whether P should take part in the project, and (b) what, in his opinion, P's wishes and feelings about taking part in the project would be likely to be if P had capacity in relation to the matter.*
- (5) *If, at any time, the person consulted advises R that in his opinion P's wishes and feelings would be likely to lead him to decline to take part in the project (or to wish to withdraw from it) if he had capacity in relation to the matter, R must ensure: (a) if P is not already taking part in the project, that he does not take part in it; (b) if P is taking part in the project, that he is withdrawn from it.*
- (6) *But subsection (5)(b) does not require treatment that P has been receiving as part of the project to be discontinued if R has reasonable grounds for believing that there would be a significant risk to P's health if it were discontinued.*
- (7) *The fact that a person is the donee of a lasting power of attorney given by P, or is P's deputy, does not prevent him from being the person consulted under this section.*
- (8) *Subsection (9) applies if treatment is being, or is about to be, provided for P as a matter of urgency and R considers that, having regard to the nature of the research and of the particular circumstances of the case: (a) it is also necessary to take action for the purposes of the research as a matter of urgency, but (b) it is not reasonably practicable to consult under the previous provisions of this section.*

- (9) *R may take the action if: (a) he has the agreement of a registered medical practitioner who is not involved in the organisation or conduct of the research project, or (b) where it is not reasonably practicable in the time available to obtain that agreement, he acts in accordance with a procedure approved by the appropriate body at the time when the research project was approved under section 31.*
- (10) *But R may not continue to act in reliance on subsection (9) if he has reasonable grounds for believing that it is no longer necessary to take the action as a matter of urgency.*

Section 33 of the MCA details important caveats on studies carried out which include participants who lack capacity:

- (1) *This section applies in relation to a person who is taking part in an approved research project even though he lacks capacity to consent to taking part.*
- (2) *Nothing may be done to, or in relation to, him in the course of the research: (a) to which he appears to object (whether by showing signs of resistance or otherwise) except where what is being done is intended to protect him from harm or to reduce or prevent pain or discomfort, or (b) which would be contrary to: (i) an advance decision of his which has effect, or (ii) any other form of statement made by him and not subsequently withdrawn, of which (in relation to both (i) and (ii)) R is aware.*
- (3) *The interests of the person must be assumed to outweigh those of science and society.*
- (4) *If he indicates (in any way) that he wishes to be withdrawn from the project he must be withdrawn without delay.*
- (5) *P must be withdrawn from the project, without delay, if at any time the person conducting the research has reasonable grounds for believing that one or more of the requirements set out in section 31(2) to (7) is no longer met in relation to research being carried out on, or in relation to, P.*
- (6) *But neither subsection (4) nor subsection (5) requires treatment that P has been receiving as part of the project to be discontinued if R has reasonable grounds for believing that there would be a significant risk to P's health if it were discontinued.*

The MCA also sets out rules dealing with the loss of capacity of a participant during a research project (see section 34 of the MCA) and the appointment and functions of 'independent mental capacity advocates' (sections 35 and 36). Please also see the Code of Practice.

The Human Tissue Act 2004 and Consent

The Human Tissue Act 2004 came into effect in 2006. For the use of tissue from patients in research studies, the consent of the patient is required except in the circumstances specified in the Act, such as when a research ethics committee has agreed to the study and the samples are anonymised.

For the use of tissue taken post mortem, the consent of the person concerned before they died, or of the relatives of the deceased, must always be obtained. As the Research Governance Framework has noted:

"Agreeing to such research involves relatives in difficult choices. Arrangements must be described for the respectful disposal of material once the research is completed, and for the reporting of the findings of the research to relatives, if they wish it."

The Human Tissue Authority is responsible for regulating and giving guidance on the storage and use of human tissue and organs.

Consent-key points

- Central to the ethics of modern research and forms the basis of protection for research subjects
- Participants must fully understand exactly what participation in the study will mean for them
- Obtaining written consent is a statutory obligation for clinical trials involving medicines
- Additional steps involved when including a person (s) who lack capacity

CLINICAL TRIALS⁷

Abbreviations & Definitions⁸

Clinical trial - is defined as any investigation in human subjects intended to:

Discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products

Identify any adverse reactions to one or more of such products

Study absorption, distribution, metabolism and excretion of one or more such products

With the object of ascertaining its safety and/or efficacy. The terms 'clinical trial' and 'clinical study' are synonymous.

Case Control- Predominantly used in epidemiological studies. This design uses retrospective comparisons about aetiology of disease. Participants who have a disease are compared to those that do not, with the aim of defining the relative contribution of one or several factors to the frequency of the disease

CRF- Case Report Form

Cross-Over Design - In this type of trial each patient acts as their own control and receives each of the treatments in sequence

CTIMP - Clinical trial of an investigational medicinal product

e CRF- Electronic Case Report Form

Double-blind - When neither the investigator nor the participant know which treatment the participant is receiving

EUDRACT- European Union Database of Clinical Trials

GCP - Good Clinical Practice

IRVS - Interactive Voice Response System

MHRA - Medicines and Healthcare Regulatory Authority

Open-label - Both the investigator and participant are aware which treatment is being given

⁷ This section of the resource pack has been co-authored by Dr Amrit Takhar, a research-active GP working with PCRN-EMSY. DR Takhar trained as a GP in Birmingham and then moved to a rural training practice at Wansford near Peterborough. He has been involved in industry research trials for 18 years and recently undertook an MSc in Information systems at Salford university during a sabbatical period in 2004. The practice is now very research active, currently recruiting to ten studies which are a mix of NHS portfolio studies as well as industry studies. He has presented at conferences on Primary care research and has facilitated several workshops on GCP in Primary care (www.wansford.co.uk/gcp) . He is also an active member of the Local Medical Committee and a member of the Northampton Commissioning executive.

⁸ Definitions taken from Fitzpatrick.S (2006) Clinical Trial Design, ICR Publishing (The Institute of Clinical Research), Bucks and Fitzpatrick.S (2006) The Clinical Trial Protocol, ICR Publishing (The Institute of Clinical Research), Bucks

Parallel Group Design - Each participant is allocated to a single treatment group throughout the study. There is usually a control group and at least one active group

Pharmacokinetics- This is the study of the time course of drug absorption, distribution, metabolism and excretion

Randomisation - the process by which participants are allocated to treatments

Single-blind - When either the investigator or participant know which treatment is being given

Stratification - In addition to randomly allocating participants to treatment groups, those participants likely to respond differently to the treatment may need to be distributed evenly to each treatment group. This process is known as stratification.

Phases of a Clinical Trial

Trials can be divided into four distinct phases namely;

- Phase 1 - Drug development in human subjects usually begins with the investigation of tolerability, pharmacokinetics and pharmacodynamics in healthy volunteers. Phase 1 trials are often referred to as 'first in man' studies
- Phase 2 - These are usually the first trials in patients with the disease to be treated, diagnosed or prevented and will be relatively short in duration. This phase of study attempts to identify the dose that produces efficacy with a minimum of side-effects
- Phase 3 - The largest and most expensive studies of the drug development process! These studies should be seeking to assess real outcomes in a variety of patients approximating to the 'real-life' population of patients who will receive the drug once it has been launched
- Phase 3b- These studies are predominantly conducted for marketing purposes and typically use the market leader as a comparator, the hope being to achieve a benefit over and above that of the existing drug

GCP: What is it?

"Good clinical practice (GCP) is a set of internationally recognised ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects⁹."

Compliance with this good practice provides assurance that the rights, safety and well-being of trial subjects are protected, and that the results of the clinical trials are credible and accurate.

⁹ Definition from EU Directive 2001/20/EC, article 1, clause 2

DECLARATION OF HELSINKI: Ethical Principles for Medical Research Involving Human Subjects¹⁰

The World Medical Association developed the Declaration of Helsinki as a statement of **ethical principles to provide guidance to physicians** and other participants in medical research involving human subjects. Medical research involving human subjects includes research on identifiable human material or identifiable data.

1. It is the **duty of the physician** to promote and safeguard the health of the people. The physician's knowledge and conscience are dedicated to the fulfilment of this duty.
2. The Declaration of Geneva of the World Medical Association binds the physician with the words, "**The health of my patient will be my first consideration,**" and the International Code of Medical Ethics declares that, "A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient."
3. **Medical progress** is based on research which ultimately must rest in part on **experimentation** involving human subjects.
4. In medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society.
5. The primary purpose of medical research involving human subjects is to improve prophylactic, diagnostic and therapeutic procedures and the understanding of the aetiology and pathogenesis of disease. Even the best proven prophylactic, diagnostic, and therapeutic methods must continuously be challenged through research for their effectiveness, efficiency, accessibility and quality.
6. **In current medical practice and in medical research, most prophylactic, diagnostic and therapeutic procedures involve risks and burdens.**
7. Medical research is subject to ethical standards that promote respect for all human beings and protect their health and rights. **Some research populations are vulnerable and need special protection.** The particular needs of the economically and medically disadvantaged must be recognized. Special attention is also required for those who cannot give or refuse consent for themselves, for those who may be subject to giving consent under duress, for those who will not benefit personally from the research and for those for whom the research is combined with care.
8. **Research Investigators should be aware of the ethical, legal and regulatory requirements for research on human subjects in their own countries as well as applicable international requirements.** No national ethical, legal or regulatory requirement should be allowed to reduce or eliminate any of the protections for human subjects set forth in this Declaration.

BASIC PRINCIPLES FOR ALL MEDICAL RESEARCH

10. It is the duty of the physician in medical research to protect the life, health, privacy, and dignity of the human subject.
11. **Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and on adequate laboratory and, where appropriate, animal experimentation.**

¹⁰ Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the 29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
and the 52nd WMA General Assembly, Edinburgh, Scotland, October 2000

12. Appropriate caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.
13. **The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol.** This protocol should be submitted for consideration, comment, guidance, and where appropriate, approval to a specially appointed ethical review committee, which must be independent of the investigator, the sponsor or any other kind of undue influence. This independent committee should be in conformity with the laws and regulations of the country in which the research experiment is performed. The committee has the right to monitor ongoing trials. The researcher has the obligation to provide monitoring information to the committee, especially any serious adverse events. The researcher should also submit to the committee, for review, information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest and incentives for subjects.
14. The research protocol should always contain a statement of the ethical considerations involved and should indicate that there is compliance with the principles enunciated in this Declaration.
15. Medical research involving human subjects should be conducted only by **scientifically qualified persons and under the supervision of a clinically competent medical person.** The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given consent.
16. Every medical research project involving human subjects should be preceded by **careful assessment of predictable risks and burdens in comparison with foreseeable benefits to the subject or to others.** This does not preclude the participation of healthy volunteers in medical research. The design of all studies should be publicly available.
17. Physicians should abstain from engaging in research projects involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians should cease any investigation if the risks are found to outweigh the potential benefits or if there is conclusive proof of positive and beneficial results.
18. Medical research involving human subjects should only be conducted if the **importance of the objective** outweighs the inherent risks and burdens to the subject. This is especially important when the human subjects are healthy volunteers.
19. Medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research.
20. **The subjects must be volunteers and informed participants** in the research project.
21. The right of research subjects to safeguard their integrity must always be respected. Every precaution should be taken to respect the privacy of the subject, the confidentiality of the patient's information and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.
22. **In any research on human beings, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail.** The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject's freely-given informed consent, preferably in writing. If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed.
23. **When obtaining informed consent for the research project the physician should be particularly cautious** if the subject is in a dependent relationship with the physician or may consent under duress. In

that case the informed consent should be obtained by a well-informed physician who is not engaged in the investigation and who is completely independent of this relationship.

24. For a research subject who is legally incompetent, physically or mentally incapable of giving consent or is a legally incompetent minor, the investigator must obtain informed consent from the **legally authorized representative in accordance with applicable law**. These groups should not be included in research unless the research is necessary to promote the health of the population represented and this research cannot instead be performed on legally competent persons.
25. When a subject deemed legally incompetent, such as a minor child, is able to give assent to decisions about participation in research, the investigator must obtain that assent in addition to the consent of the legally authorized representative.
26. Research on individuals from whom it is not possible to obtain consent, including proxy or advance consent, should be done only if the physical/mental condition that prevents obtaining informed consent is a necessary characteristic of the research population. The specific reasons for involving research subjects with a condition that renders them unable to give informed consent should be stated in the experimental protocol for consideration and approval of the review committee. The protocol should state that consent to remain in the research should be obtained as soon as possible from the individual or a legally authorized surrogate.
27. **Both authors and publishers have ethical obligations**. In publication of the results of research, the investigators are obliged to preserve the accuracy of the results. **Negative as well as positive results should be published or otherwise publicly available**. Sources of funding, institutional affiliations and any possible conflicts of interest should be declared in the publication. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.

ADDITIONAL PRINCIPLES FOR MEDICAL RESEARCH COMBINED WITH MEDICAL CARE

28. The physician may combine medical research with medical care, only to the extent that the research is justified by its potential prophylactic, diagnostic or therapeutic value. When medical research is combined with medical care, additional standards apply to protect the patients who are research subjects.
29. The benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods. This does not exclude the use of placebo, or no treatment, in studies where no proven prophylactic, diagnostic or therapeutic method exists. [See footnote](#)
30. At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study. [See footnote](#)
31. The physician should fully inform the patient which aspects of the care are related to the research. The refusal of a patient to participate in a study must never interfere with the patient-physician relationship.
32. In the treatment of a patient, where proven prophylactic, diagnostic and therapeutic methods do not exist or have been ineffective, the physician, with informed consent from the patient, must be free to use unproven or new prophylactic, diagnostic and therapeutic measures, if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. Where possible, these measures should be made the object of research, designed to evaluate their safety and efficacy. In all cases, new information should be recorded and, where appropriate, published. The other relevant guidelines of this Declaration should be followed.

First note of clarification on paragraph 29 of the WMA Declaration of Helsinki

The WMA hereby reaffirms its position that extreme care must be taken in making use of a placebo-controlled trial and that in general this methodology should only be used in the absence of existing proven therapy. However, a placebo-controlled trial may be ethically acceptable, even if proven therapy is available, under the following circumstances:

- Where for compelling and scientifically sound methodological reasons its use is necessary to determine the efficacy or safety of a prophylactic, diagnostic or therapeutic method; or - Where a prophylactic, diagnostic or therapeutic method is being investigated for a minor condition and the patients who receive placebo will not be subject to any additional risk of serious or irreversible harm.

All other provisions of the Declaration of Helsinki must be adhered to, especially the need for appropriate ethical and scientific review.

Second note of clarification on paragraph 30 of the WMA Declaration of Helsinki

The WMA hereby reaffirms its position that it is necessary during the study planning process to identify post-trial access by study participants to prophylactic, diagnostic and therapeutic procedures identified as beneficial in the study or access to other appropriate care. Post-trial access arrangements or other care must be described in the study protocol so the ethical review committee may consider such arrangements during its review

Key Principles

Conducted according to ethical principles	1. Clinical trials shall be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with good clinical practice and the requirements of these Regulations.
Risks and benefits are considered before starting trials	2. Before the trial is initiated, foreseeable risks and inconveniences have been weighed against the anticipated benefit for the individual trial subject and other present and future patients. A trial should be initiated and continued only if the anticipated benefits justify the risks.
Rights of patients are more important than other factors	3. The rights, safety, and well-being of the trial subjects are the most important considerations and shall prevail over interests of science and society .
Relevant information available	4. The available non-clinical and clinical information on an investigational medicinal product shall be adequate to support the clinical trial.
Scientific basis	5. Clinical trials shall be scientifically sound, and described in a clear, detailed protocol.
Ethics committee MUST approve any trial	6. A trial shall be conducted in compliance with the protocol that has a favourable opinion from an ethics committee.

Doctor must remain responsible for medical care	7. The medical care given to, and medical decisions made on behalf of, subjects shall always be the responsibility of an appropriately qualified doctor or, when appropriate, of a qualified dentist.
Education and training of those involved in trials	8. Each individual involved in conducting a trial shall be qualified by education, training, and experience to perform his or her respective task(s).
Informed consent	9. Subject to the other provisions of this Schedule relating to consent, freely given informed consent shall be obtained from every subject prior to clinical trial participation.
Trial Information	10. All clinical trial information shall be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.
Confidentiality and data protection	11. The confidentiality of records that could identify subjects shall be protected, respecting the privacy and confidentiality rules in accordance with the requirements of the Data Protection Act 1998 and the law relating to confidentiality.
Manufacturing practice	12. Investigational medicinal products used in the trial shall be - (a) manufactured or imported, and handled and stored, in accordance with the principles and guidelines of good manufacturing practice, and (b) used in accordance with the approved protocol.
Quality assurance	13. Systems with procedures that assure the quality of every aspect of the trial shall be implemented.

ADVERSE EVENTS IN RESEARCH

What are they?

Adverse Events in Non-Clinical Research Projects

For the purposes of this document, the term **Non-Clinical Adverse Event** applies to Observational and Non-Clinical studies. The definition encompasses (but is not limited to):

- An unanticipated problem that involves risk to the participants
- Protocol deviations that might entail risk to the participants
- 'Unanticipated risk' includes new risk, and increased incidence of anticipated risks¹¹

Reasonable judgment must be used to determine what a **Non-Clinical Serious Adverse Event** would constitute. The event may not be a physical occurrence. It is suggested that particular attention be paid, but not limited to:

- Research Fraud and Misconduct
- Threats to Privacy and/or Subject Safety
- Patient Complaint likely to lead to litigation
- An event that has legal or economic ramifications
- Would result in a change to the Protocol, Participant Information Sheet or Consent Form

Adverse Events in Clinical, Medicinal Product or Medical Device Trials

An adverse event (AE) is defined by ICH-GCP¹² as:

- Any new, undesirable event occurring to a subject during a clinical trial, whether or not considered related to the investigation product (s) and or device
- It is generally held that abnormal laboratory values are not considered to be AE's, however, any clinical consequences arising from them should be reported as adverse events.
- Elective hospitalisations for pre-trial conditions are not adverse events.
- An adverse reaction to an investigational medicinal product (AR) includes¹³ all untoward and unintended responses to an investigational medicinal product related to any dose administered.

¹¹ Adapted for use from John Hopkins University (2000) *Committee on Human Research-Reporting of Adverse and or Unexpected Events*, John Hopkins University, California.

¹² International Council for Harmonisation (1990) *ICH Harmonised Tripartite Guideline for Good Clinical Practice*, Brookwood Medical Publications, Surrey.

¹³ European Commission ENTR/F2/BL D (2003) *Detailed guidance on the collection, verification, and presentation of adverse reaction reports arising from clinical trials on medicinal products for human use*, European Commission, Brussels.

- An Unexpected Adverse Reaction (UAR) is said to have occurred when the nature or severity of which is not consistent with the applicable product information (e.g. the Investigator Brochure for an unauthorised investigational product, or summary of product characteristics for an authorised product).
- All adverse events judged by either the reporting investigator or the study sponsor as having a reasonable causal relationship to a medicinal product qualify as adverse reactions.
- All adverse events occurring during the study should be recorded in the subject case report form and in the medical notes.

A serious adverse event (SAE) or serious adverse reaction is defined by the regulatory agencies as one that suggests a significant hazard or side effect and results in any of the following six outcomes. A serious adverse event/reaction occurs during investigation of a medicinal product (plus its comparators), device, or treatment.

Suspected Unexpected Serious Adverse Reactions (SUSARS) are generally held to be events resulting in any of the following six outcomes, with the nature or severity being inconsistent with the applicable product information (as outlined in Unexpected Adverse Reaction),

- Death
- A life threatening adverse experience that places the subject, in the view of the investigator, at immediate risk of death from the adverse event
- Requires or prolongs inpatient hospitalisation
- Results in persistent or significant disability/incapacity. *This criterion applies if the "disability" caused by the reported adverse event results in a substantial disruption of a person's ability to conduct normal life functions*
- A congenital anomaly/birth defect

Important medical events that may not result in death, be life threatening, or require hospitalisation may be considered a serious adverse experience when, based upon appropriate medical judgement, they may jeopardise the subject and may require medical or surgical intervention to prevent one of these outcomes

Additionally, for Medical Devices or Equipment:

- Any incident that was linked to the device or shortcomings in the information provided, that might lead to death or serious deterioration in health if it recurred
- Any malfunction of a device used in accordance with the manufacturer's instructions, for which the manufacturer has not made provision, and which causes an injury or potential injury
- Inaccuracies or omissions in the manufacturer's instructions that caused, or had the potential to cause, misuse or incorrect maintenance or adjustment¹⁴

¹⁴ University Hospital Birmingham NHS Trust (2001) *Policy on Safety Reporting in Biomedical Research involving Human Subjects*, University Hospital Birmingham NHS Trust, Birmingham.

DATA MANAGEMENT

Research records need to be maintained and preserved for a number of reasons. *The Research Governance Framework for Health and Social Care, second edition (2005)*¹ states that;

“data collected in the course of research must be retained for an appropriate period to allow for further analysis by the original or other research teams subject to consent¹⁵, and to support monitoring / auditing of good research practice by regulatory or other agencies”.

Furthermore, researchers should be mindful that appropriate management and retention of research records also applies under the following;

*Directive 2001/20/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use*²
*ICH-GCP (International Conference on Harmonisation Guidelines for Good Clinical Practice 1996)*³
*Freedom of Information Act (2000)*⁴

It is, therefore, the responsibility of the Chief/Principal Investigator to ensure that suitable arrangements are made to archive all research data.

Patient information is generally held under the legal and ethical obligations of confidentiality, with the ‘right to privacy’ being one of the founding principles of the *Human Rights Act (1998)*. Under English Law, the collection, processing and storage of personal data is governed by the *Data Protection Act (1998)*⁵. Within the NHS environment, researchers also have an obligation to comply with the *Access to Health Records Act (1990)*, *NHS Code of Confidentiality (2003)*⁶ and Caldicott Principles.

Definitions

Archiving - The long-term storage of study data/documentation in a safe, secure environment for the period agreed at the study outset (in accordance with study protocols and local arrangements).

Chief Investigator (CI)⁷ - In relation to a research project conducted at more than one research site; the authorised health care professional who takes primary responsibility for the conduct of the research (whether or not he/she is an investigator at any particular site).

Custodian of data - A designated individual (normally the CI/PI) entrusted/appointed with the responsibility of guarding/safekeeping and storage of all study related data/documentation-ensuring access only to authorised personnel and in accordance with Data Protection guidance.

Clinical trial³ - any investigation in human subjects intended to;

- discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products.
- identify any adverse reactions to one or more of such products.
- study absorption, distribution, metabolism and excretion of one or more such products

with the objective of ascertaining the safety, or efficacy, of those products. The terms clinical trial and clinical study are synonymous.

¹⁵ Regulations under Section 251 NHS Act (2006) specify the very limited circumstances when identifiable patient information may be used for research purposes without consent

Destruction - is defined as the shredding or incineration of study documents and files on or soon after the designated destruction date has been reached.

Data - includes but is not limited to written and electronic records, opinions, images, recordings and information gained from biomedical samples.

End of study⁷ - is defined as the last visit of the last participant, unless otherwise specified in the protocol or the date of the last data collection/entry.

Human Tissue⁸ - Human tissue can be defined as material other than gametes, which consist of, or include human cells. It does not include embryos outside the human body, or hair and nail from a living person. This also excludes cell lines and other human material created outside the human body.

Identifiable Data - Data that can identify an individual directly or can be used to determine an individual's identity. This may also include linked or Pseudoanonymised data; this like non-identifiable data in that the possession of the holder, it cannot be reasonably used to identify an individual. However, it differs in that the original provider of the information may retain a means of identifying individuals. This will often be achieved by attaching codes or other unique references to information so that the data will only be identifiable to those who have access to the key or index

Non-identifiable data - Information that does not identify an individual directly, and which cannot reasonably be used to determine identity. This includes the removal of name, address, full postcode and any other detail or combination of details that might support identification. This may also be referred to as anonymised or non-linked data

Personal data - data that relates to a living individual who can be identified from that data, or from data in possession of, or likely to come into possession of the data controller (researcher, research team member).

Principal Investigator (PI)⁷ - The authorised health care professional responsible for the conduct of a research project at a research site. If a team of healthcare professionals conducts the research, the PI is the investigator responsible for that team.

Research site - The organisation or unit responsible for conducting the research at a particular locality.

Sensitive information - is defined in the Data Protection Act, as information relating to; racial or ethnic origin, political opinions, religious beliefs (or beliefs of a similar nature), membership of a Trade Union, physical or mental health or condition, sexual activity, commission or alleged commission of criminal activity, or any proceedings for any offence committed or alleged to have been committed by him.

Student research - Research conducted as part of an educational program.

Study Site File - Contains all documents that individually, and collectively, permit evaluation of the conduct of a research project and the quality of the data produced. A Study Site File may also be referred to an Investigator File / Project Master File / Site Master File or Trial Master file, but for the purposes of this document serve the same function. All studies are expected to have study site file containing the core documents listed in Appendix A; with the exception of Clinical Trials using an investigational medicinal product, and which is registered with the Medicines and Healthcare products Regulatory Authority (MHRA) - these trials are required to have a study site file containing the Essential Documents listed in Appendix B.

Staff - For the purposed of this document, 'staff' is defined to include those working on a full-time, part-time, salaried or honorary basis. It also includes Independent Contractors and their staff.

Sponsor - This is the organisation or person who takes responsibility for the initiation, management and financing (or arranging the financing) of that trial.

Procedures: General Data

Each study will see collected various forms of data throughout the course of its life. Data collected will be a combination of identifiable and non-identifiable, source or original and transcribed - whatever the data source, it must be managed in accordance with these general principles:

- Before a researcher can access or collect any data, the Trust Research and Development Department or Comprehensive Local Research Network, and the relevant Research Ethics Committee must approve the research project in writing.
- Collect only data specifically required for the purposes of the research project.
- Personal data that is provided for health care, or obtained in health services/medical research, must be regarded as confidential.

The Data Protection Act applies to data relating to a living individual who can be identified from the data; or from other data and information where it would be easy to link the individual with the data concerned. There is a statutory obligation to apply an 'audit trail' to any data that comes under the Act. It is considered good practice to apply the same stringent processes to all other types of research data.

- All data must be stored in a safe and secure environment that cannot be accessed by unauthorised persons. This is applicable for the duration of the project and for the specified archive period following completion.
- As a minimum requirement, the: five basic, Eight Data Protection and Six Caldicott principles must be adhered to when collecting information about a research participant (this also applies to staff who may be research participants). These principles are contained in Appendix C.
- Clinical Trials involving 'Investigational Medicinal Products' must be approved by the Medicines and Healthcare products Regulatory Authority (MHRA) and conform to the *EU Directive on Clinical Trials* and Good Clinical Practice when collecting, managing and archiving research data

Roles and Responsibilities

Core Documents

Chief/Principal Investigators are required to keep, and maintain, a CORE set of documents (see Appendix A) for EACH research project they manage. All core documents should be kept in a designated file called a Site Master File (or local equivalent). These serve to demonstrate good research practice, but do not fall under the requirements of the EU Clinical Trials Directive.

In addition to the above, if a study falls within the jurisdiction of the EU Clinical Trials Directive, then the list of CORE documents (Appendix A) is superseded by a list of ESSENTIAL documents (Appendix B) The researcher then has a statutory requirement to adhere to Good Clinical Practice (GCP) and maintain the essential documents.

Access to Core Documents and Source Data/Documents

Only members of the study team, the appropriate regulatory and inspection bodies and those specified in R&D and ethics approved documentation, have the right to access study data, whether this data is capable of identifying the participant or not.

The researcher may employ only the method of data access and collection specified in the approved project protocol. The R&D Department and the relevant Research Ethics Committee must approve any subsequent amendment, generally in writing.

Under the Research Governance Framework the CI/PI is required to implement procedures to ensure the collection of accurate, high quality data and that the integrity and confidentiality of that data is protected at all times.

Changes or corrections to study data

Any change or correction to study data should be dated, initialled and explained (if necessary) and should not obscure the original entry (i.e. an audit trail should be maintained); this applies to both written and electronic changes and corrections.

Location of study data whilst project in progress

All study data (including identifiable and non-identifiable material) must be kept in a safe and secure location, accessible only by the study team. It is essential that study data is never in a position where confidentiality can be breached, unauthorised access could place, or unauthorised alteration can be made; otherwise data integrity cannot be assured.

Transferring data to a third party

Data should not be passed to anyone outside of the research team. If data transfer is a requirement of the project, the transfer details must be submitted, and agreed, as part of the project R&D and ethics approval processes. In the case of human tissue leaving the Trust, a Material Transfer Agreement may be required. Please contact the R&D Department for further information and advice.

Access to identifiable Patient Medical Health Records

If a researcher wishes to access identifiable patient medical health records solely for the purposes of research, prior authorisation must be obtained according to local Trust arrangements. It is not acceptable to access patient records via any other route. The Trust will not release any information unless the project has received both R&D and research ethics committee approval. Any researcher requesting medical health records must either be employed by the Trust; hold an Honorary Trust Contract or R & D Confidentiality Letter AND have patient consent or NIGB¹⁶ approval.

It is likely that research data will be stored, generated or accessed electronically. In addition to the 'general principles' of data protection and Appendix 3 of this document, the following steps should be followed:

Ensure that the correct authorisation has been obtained to access the data;

Do not use someone else's password, or name, to access data.

Encrypt data wherever possible.

It is strongly recommended that researchers use a unique study number for individual participants rather than entering participant identifiable data onto a computer

Password protect documents and databases

Keep computer in a safe and secure environment.

Images required for research purposes must be obtained and kept in accordance with local policy.

Do not send identifiable information through the Internet unless it is via a Trust approved secure system.

Information should be protected by clearly defined and controlled backup as defined by local Trust policies and procedures.

¹⁶ The NIGB is an independent statutory body established to promote, improve and monitor information governance in health and social care. The NIGB provides advice on the appropriate use, sharing and protection of patients and service user information. The NIGB also advises on the use of powers under Section 251 of the NHS Act 2006. Its membership is drawn from public and representative members. <http://www.nigb.nhs.uk/>

Backups must be held in a secure location with protection from fire and theft.

Management of Source Data

Source Data is defined in ICH/GCP as all information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).

Every research project is different and data will be collected in a variety of ways, including but not limited to: Paper, Audio Tape, Video, and Photographic/Web Camera. It is therefore important to remember that the primary method of collection of any data is the original source i.e. the very FIRST TIME that the data was recorded.

Generally source data consists of original documents such as:

- Medical Health Records and GP Notes
- Clinical charts
- Laboratory notes
- Subjects' diaries
- Visit appointment diaries

Examples of Source Documents

It also includes more specific documents such as:

- Consent forms
- Questionnaires
- Pharmacy dispensing records
- Recorded data from automated instruments, e.g. ECG
- Tapes of interview recordings
- Transcriptions certified after verification as being accurate and complete
- Photographic negatives, microfilm or magnetic media^{9/10}
- X-rays, Scan pictures and reports
- Laboratory Sample Logs, Freezer Books
- General Practitioner Letter/Records
- Laboratory reports and records kept at the laboratories

It should be noted that the above list is not exhaustive, but highlights the types of documents that should be considered as source data if used as part of the data collection process during the study.

Data Archiving Process

The *Research Governance Framework* states that it is the responsibility of the Chief/Principal Investigator to make suitable arrangements for the appropriate archiving of study data.

Pre-archiving points to consider

Archiving retention periods vary depending on the nature of the research project conducted. Therefore, as a general rule the following is recommended - If the study is a clinical trial for either a first Marketing Authorisation, or an amendment to an existing Marketing Authorisation, then data should be held in accordance with ICH-GCP. For all other research, data must be retained for TEN Years following completion of the project or 'End of Study'. If, however, another Organisation has the responsibility of acting as Sponsor, archiving should be in accordance with their requirements and/or policies and procedures.

When working with commercial partners it is advisable to discuss data archiving as early as possible during the research process. Due to limited 'Trust' storage space, it is a recommendation that the Chief / Principal Investigator asks the company to arrange off-site archiving of study data at the end of the project.

CI/PI are required to clearly identify the medical records of patients taking part in research projects¹⁷. The suggested process for this is to place a sticker on the front/or inside¹⁸ cover of the records that denotes: the patient is in a research study and the date the notes will no longer be required for research purposes. If subsequent to this, the patient takes part in another study, and the retention period for this project is after the original date, another sticker, displaying the new date should be placed on top of the old one (the longer time period always taking precedent). It is essential that records for patients involved in research studies or clinical trials are not microfiched, or electronically scanned, in order to preserve them in their original format.

The Chief / Principal Investigator must also inform any other departments involved in the study, of the requirements regarding the source data that should be retained, as well as the retention period.

Study data must remain accessible and available for inspection and auditing purposes to both the Trust and any other recognised regulatory body.

The storage facility must be secure, with appropriate environmental controls and adequate protection from fire, flood and unauthorised access.

Identifiable data must not be archived on home premises

Archiving Process

- For electronically held identifiable data, the files should be encrypted prior to archiving. The encrypted files will each have a code, an 'encryption key', which must be stored separately to the electronic data files.
- Compress electronic files to save space, by using an application such as WINZIP. The data should then be saved onto a Compact-disc recordable-read only memory (CD-R¹⁹). Small electronic data sets could be stored on floppy disc.
- The 'subject identification key' linking participants to codes must be archived separately to the coded data.
- Put data and documents for archiving in numbered and labelled boxes²⁰ An inventory listing the individual boxes contents should be drafted - place one copy in the corresponding box, and retain a second copy to be held by the CI/PI (to form a log).
- Seal the archiving boxes with tape, and sign across a sealed area.
- Deliver to secure archiving facility²¹.

Post Archiving

- The Chief/ Principal Investigator must maintain a log of archived documents, their location and destruction date. These records must remain in the appropriate location even if the member of staff leaves the Trust/ Department. In addition the responsibility of maintaining the log must be passed on to another member of staff.

Destruction

- The Trust R & D Department must be contacted prior to the disposal of any research documents

¹⁷ This process is classified as an Administrative rather than a Clinical alert

¹⁸ The research sticker should be placed either on the front, or inside, cover of the patients notes depending on local Trust policy/procedure

¹⁹ Data integrity is only guaranteed for 5 years on CD-ROM. CD's should be copied after this time period has elapsed

²⁰ The Trust recommends that each box be labelled twice, once on short side and once on long side. The labels should be written in indelible ink and contain the following information: Box number, CI/PI name, Project title and reference number, and date of destruction

²¹ If being archived off-site, a record must be kept detailing the location and company details

- On or soon after the designated destruction date, documents and files containing personal data should be shredded or incinerated.
- The person responsible for shredding or incinerating the documents / electronic records should sign the original archiving log²² by to verify that destruction has taken place.

Appendix A

Core Documents to be retained as a minimum for all research projects

Documents to be Maintained	Rationale	Location
<ul style="list-style-type: none"> • Copy of Trust R&D approval letter • Copy of the appropriate ethics approval letter. • Copies of any amendment approval/acknowledgment letters. 	To demonstrate that the correct approval has been given by the R&D Dept and relevant ethics committee	T/PMF
<ul style="list-style-type: none"> • Approved protocol, including any amendments. 	To ensure that the correct, approved version is being used	T/PMF
<ul style="list-style-type: none"> • Copy of the approved consent form, information sheet, ward information sheet, GP letter 	This ensures that: <ul style="list-style-type: none"> • correct, approved version is being used • to inform ward staff of the project, and what it entails • the patients GP has been notified 	T/PMF
<ul style="list-style-type: none"> • Copy of the Case Report Forms (CRF's) or data collection proformas in use 	<ul style="list-style-type: none"> • the correct, approved version is being used 	T/PMF
<ul style="list-style-type: none"> • Original signed consent forms (give a copy to patient and put a copy in the notes) 	<ul style="list-style-type: none"> • to verify that consent has been obtained prior to participation in the study 	T/PMF Use separate box file if needed
<ul style="list-style-type: none"> • Creation of a Participant Identification Log, which includes the allocation of a unique study code or number 	Provides a confidential list of all study participants who are identifiable by their names, hospital numbers, dates of birth etc, and what their allocated code or study number is (which should be used in lieu of the participants personal identification)	T/PMF

²² It is advisable to retain the original archiving log indefinitely as evidence that proper procedure has been followed

<ul style="list-style-type: none"> Completed CRF's, data collection proformas, questionnaires etc- identify by study code or number wherever possible 	<ul style="list-style-type: none"> To demonstrate that relevant data has been collected and recorded for each participant. 	T/PMF Use separate box file if needed
<ul style="list-style-type: none"> Source documents/data -(original documents, data and records e.g. medical records, recorded data from automated machines, blood results, x-rays, pharmacy dispensing records etc, documented medical history) 	<ul style="list-style-type: none"> To document the existence of the participant and substantiate integrity of project data that has been collected 	T/PMF or in relevant dept
<ul style="list-style-type: none"> List of all study personnel involved in the study, including their signature, initials and study responsibilities. 	<ul style="list-style-type: none"> To identify signatures appearing on study documents Provides a list all persons authorised to make such entries and their project responsibilities. 	T/PMF

<ul style="list-style-type: none"> Adverse Event and Serious Adverse Event Record sheets. (All AE's must be recorded and reported in accordance with local policy) 	All adverse events must be recorded and reported, as appropriate, in accordance with host organisational requirements (and that of the funder/sponsor should these differ).	T/PMF
<ul style="list-style-type: none"> Drug storage and administration management process Drug administration or tracking form (if applicable) 	<ul style="list-style-type: none"> To document process of storage, dispensing administration and disposal of study medication. 	T/PMF
<ul style="list-style-type: none"> Registration certificates e.g. Clinical Trials Authorisation. 	<ul style="list-style-type: none"> To demonstrate the project is correctly registered with the appropriate authority and that it complies with regulatory requirements 	T/PMF
<ul style="list-style-type: none"> Standard Operating Procedure for any medical/laboratory or technical procedure and validity/service records 	<ul style="list-style-type: none"> To document competence of a piece of equipment to perform the required task and support reliability of results To document how a procedure is performed or carried out 	T/PMF

<ul style="list-style-type: none"> All correspondence, emails or notes relating to the study 	<ul style="list-style-type: none"> To identify and produce an audit trail of any agreements or significant discussions regarding project administration, protocol deviation, project conduct or adverse event etc 	T/PMF
<ul style="list-style-type: none"> Curriculum vitae of Chief/Principle and Co-investigators 	<ul style="list-style-type: none"> To demonstrate that staff are qualified to undertake their specific roles in the project by education, training or experience. A CV will contain documented evidence of training, qualifications and previous experience 	T/PMF

Appendix B

Essential Documents required under GCP Guidelines

Essential documents are documents that individually and collectively permit the evaluation of the conduct of a study and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor and monitor with the standards of Good Clinical Practice. They are also the documents usually audited by the sponsor's independent audit function and inspected by the regulatory authority(ies) as part of the process to confirm the validity of the trial conduct and the integrity of the data collected.

ICH Harmonised Tripartite Guidelines for Good Clinical Practice 1996

Title of Document (number donates section to refer to the Guideline document)	Purpose	Located in Files of:	
		Investigator/ Sponsor Institution	
8.2.1 INVESTIGATOR'S BROCHURE	To document that relevant and current scientific information about the investigational product has been provided to the investigator	X	X
8.2.2 SIGNED PROTOCOL AND AMENDMENTS, IF ANY, AND SAMPLE CASE REPORT FORM (CRF)	To document investigator and sponsor agreement to the protocol/amendment(s) and CRF	X	X
8.2.3 INFORMATION GIVEN TO TRIAL SUBJECT -INFORMED CONSENT FORM (including all applicable translations) -ANY OTHER WRITTEN INFORMATION	1. To document the informed consent 2. To document that subjects will be given appropriate written information (content and wording) to	X	X

-ADVERTISEMENT FOR SUBJECT RECRUITMENT (if used)	support their ability to give fully informed consent 3. To document that recruitment measures are appropriate and not coercive	X X	
8.2.4 FINANCIAL ASPECTS OF THE TRIAL	To document the financial agreement between the investigator/institution and the sponsor for the trial	X	X
8.2.5 INSURANCE STATEMENT (where required)	To document that compensation to subject(s) for trial-related injury will be available	X	X
8.2.6 SIGNED AGREEMENT BETWEEN INVOLVED PARTIES, e.g. : - investigator/institution and sponsor - investigator/institution and CRO - sponsor and CRO investigator/institution and authority(ies) (where required)	To document agreements	X X X	X X X(where needed) X

8.2.7 DATED, DOCUMENTED APPROVAL/FAVOURABLE OPINION OF INSTITUTIONAL REVIEW BOARD (IRB) IRB/IEC /INDEPENDENT ETHICS COMMITTEE (IEC) OF THE FOLLOWING: - protocol and any amendments - CRF (if applicable) - informed consent form(s) - any other written information to be provided to the subject(s) - advertisement for subject recruitment(if used) - subject compensation (if any) - any other documents given approval/favourable opinion	To document that the trial has been subject to review and given approval/favourable opinion. To identify the version number and date of the document(s).	X	X
8.2.8 INSTITUTIONAL REVIEW BOARD/INDEPENDENT ETHICS COMMITTEE COMPOSITION	To document that the IRB/IEC is constituted in agreement with GCP	X	X (where required)
8.2.9 REGULATORY AUTHORITY(IES) AUTHORISATION/APPROVAL/ NOTIFICATION OF PROTOCOL (where required)	To document appropriate authorisation/approval/notification by the regulatory authority(ies) has been	X (where required)	X (where required)

	obtained prior to initiation of the trial in compliance with the applicable regulatory requirement(s))
8.2.10 CURRICULUM VITAE AND/OR OTHER RELEVANT DOCUMENTS EVIDENCING QUALIFICATIONS OF INVESTIGATOR(S) AND SUB-INVESTIGATOR(S)	To document qualifications and eligibility to conduct trial and/or provide medical supervision of subjects	X	X
8.2.11 NORMAL VALUE(S)/RANGE(S) FOR MEDICAL/LABORATORY/TECHNICAL PROCEDURE(S) AND/OR TEST(S) INCLUDED IN THE PROTOCOL	To document normal values and/or ranges of the tests	X	X
8.2.12 MEDICAL/LABORATORY/TECHNICAL PROCEDURES /TESTS - certification or - accreditation or - established quality control and/or external quality assessment or - other validation (where required)	To document competence of facility to perform required test(s), and support reliability of results	X (where required)	X
8.2.13 SAMPLE OF LABEL(S) ATTACHED TO INVESTIGATIONAL PRODUCT CONTAINER(S)	To document compliance with applicable labelling regulations and appropriateness of instructions provided to the subjects		X
8.2.14 INSTRUCTIONS FOR HANDLING OF INVESTIGATIONAL PRODUCT(S) AND TRIAL-RELATED MATERIALS (if not included in protocol or Investigator's related materials Brochure)	To document instructions needed to ensure proper storage, packaging, dispensing and disposition of investigational products and trial	X	X
8.2.15 SHIPPING RECORDS FOR INVESTIGATIONAL PRODUCT(S) AND TRIAL-RELATED MATERIALS	To document shipment dates, batch numbers and method of shipment of investigational product(s) and trial-related materials. Allows tracking of product batch, review of shipping conditions, and accountability	X	X
8.2.16 CERTIFICATE(S) OF ANALYSIS OF INVESTIGATIONAL PRODUCT(S) SHIPPED	To document identity, purity, and strength of investigational product(s) to be used in the trial		X
8.2.17 DECODING PROCEDURES FOR BLINDED TRIALS	To document how, in case of an emergency, identity of blinded investigational product can be revealed without breaking the blind for the remaining subjects' treatment	X	X (third party if applicable)
8.2.18 MASTER RANDOMISATION LIST	To document method for randomisation		X

	of trial population		(third party if applicable)
8.2.19 PRE-TRIAL MONITORING REPORT	To document that the site is suitable for the trial (may be combined with 8.2.20)		X
8.2.20 TRIAL INITIATION MONITORING REPORT	To document that trial procedures were reviewed with the investigator and the investigator's trial staff (may be combined with 8.2.19)	X	X

Acknowledgements

This section is largely based on the Data Management guidance produced by the Trent Research Governance Best Practice Group (RGBPG) comprising of research governance managers from Derby Hospitals Foundation Trust, NHS Nottinghamshire County, Nottinghamshire Healthcare Trust, Nottingham University Hospitals Trust and United Lincolnshire Hospitals.

Nottinghamshire County Teaching Primary Care Trust

Best Practice Guidance: Data Management in Research

Reader information

Reference	RD/04
Directorate	Nursing and Integrated Governance
Document purpose	To provide researchers with a simple guide on how to manage research data in accordance with good research practice
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Title	<i>Best Practice Guidance: Data Management in Research</i>
Author/Nominated Lead (Title plus contact details)	Research Governance Best Practice Group (RGBPG)/ Nathalie Bailey-Flitter, Research Governance Coordinator, Hucknall Health Centre, Hucknall
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1. Introduction

This document has been developed to provide researchers with a simple guide on how to manage research data in accordance with good research practice. Any research carried out within this Trust: involving patients, staff, their tissue, data or organs or using any Trust facilities, should adhere to the principles outlined within this guidance.

2. Statement of intent

Research records need to be maintained and preserved for a number of reasons. *The Research Governance Framework for Health and Social Care, second edition (2005)*¹ states that;

“data collected in the course of research must be retained for an appropriate period to allow for further analysis by the original or other research teams subject to consent²³, and to support monitoring / auditing of good research practice by regulatory or other agencies”.

Furthermore, researchers should be mindful that appropriate management and retention of research records also applies under the following;

*Directive 2001/20/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use*²
*ICH-GCP (International Conference on Harmonisation Guidelines for Good Clinical Practice 1996)*³
*Freedom of Information Act (2000)*⁴

It is, therefore, the responsibility of the Chief/Principal Investigator to ensure that suitable arrangements are made to archive all research data.

Patient information is generally held under the legal and ethical obligations of confidentiality, with the ‘right to privacy’ being one of the founding principles of the *Human Rights Act (1998)*. Under English Law, the collection, processing and storage of personal data is governed by the *Data Protection Act (1998)*⁵. Within the NHS environment, researchers also have an obligation to comply with the *Access to Health Records Act (1990)*, *NHS Code of Confidentiality (2003)*⁶ and Caldicott Principles.

All Trust staff should follow these guidelines. They also seek to serve as guidance to those who are not members of the Trust, (including all students), but are authorised to conduct research within the Trust. They should be interpreted in a manner consistent with all other Trust Policies.

3. Definitions

²³ Regulations under Section 60 of the Health and Social Act (2001) specify the very limited circumstances when identifiable patient information may be used for research purposes without consent

Archiving – The long-term storage of study data/documentation in a safe, secure environment for the period agreed at the study outset (in accordance with study protocols and local arrangements).

Chief Investigator (CI)⁷ – In relation to a research project conducted at more than one research site; the authorised health care professional who takes primary responsibility for the conduct of the research (whether or not he/she is an investigator at any particular site).

Custodian of data – A designated individual (normally the CI/PI) entrusted/appointed with the responsibility of guarding/safekeeping and storage of all study related data/documentation-ensuring access only to authorised personnel and in accordance with Data Protection guidance.

Clinical trial³ - any investigation in human subjects intended to;

- discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products.
- identify any adverse reactions to one or more of such products.
- study absorption, distribution, metabolism and excretion of one or more such products

with the objective of ascertaining the safety, or efficacy, of those products. The terms clinical trial and clinical study are synonymous.

Destruction – is defined as the shredding or incineration of study documents and files on or soon after the designated destruction date has been reached.

Data - includes but is not limited to written and electronic records, opinions, images, recordings and information gained from biomedical samples.

End of study⁷ – is defined as the last visit of the last participant, unless otherwise specified in the protocol or the date of the last data collection/entry.

Human Tissue⁸ –Human tissue can be defined as material other than gametes, which consist of, or include human cells. It does not include embryos outside the human body, or hair and nail from a living person. This also excludes cell lines and other human material created outside the human body.

Identifiable Data – Data that can identify an individual directly or can be used to determine an individual's identity. This may also include linked or Pseudoanonymised data; this like non-identifiable data in that the possession of the holder, it cannot be reasonably used to identify an individual. However, it differs in that the original provider of the information may retain a means of identifying individuals. This will often be achieved by attaching codes or other unique references to information so that the data will only be identifiable to those who have access to the key or index

Non-identifiable data – Information that does not identify an individual directly, and which cannot reasonably be used to determine identity. This includes the removal of name, address, full postcode and any other detail or combination of details that might support identification. This may also be referred to as anonymised or non-linked data

Personal data - data that relates to a living individual who can be identified from that data, or from data in possession of, or likely to come into possession of the data controller (researcher, research team member).

Principal Investigator (PI)⁷ - The authorised health care professional responsible for the conduct of a research project at a research site. If a team of healthcare professionals conducts the research, the PI is the investigator responsible for that team.

Research site – The organisation or unit responsible for conducting the research at a particular locality.

Sensitive information - is defined in the Data Protection Act, as information relating to; racial or ethnic origin, political opinions, religious beliefs (or beliefs of a similar nature), membership of a Trade Union, physical or mental health or condition, sexual activity, commission or alleged commission of criminal activity, or any proceedings for any offence committed or alleged to have been committed by him.

Student research – Research conducted as part of an educational program.

Study Site File – Contains all documents that individually, and collectively, permit evaluation of the conduct of a research project and the quality of the data produced. A Study Site File may also be referred to an Investigator File / Project Master File / Site Master File or Trial Master file, but for the purposes of this document serve the same function. All studies are expected to have study site file containing the core documents listed in Appendix A; with the exception of Clinical Trials using an investigational medicinal product, and which is registered with the Medicines and Healthcare products Regulatory Authority (MHRA) – these trials are required to have a study site file containing the Essential Documents listed in Appendix B.

Staff – For the purposes of this document, 'staff' is defined to include those working on a full-time, part-time, salaried or honorary basis. It also includes Independent Contractors and their staff.

Sponsor – This is the organisation or person who takes responsibility for the initiation, management and financing (or arranging the financing) of that trial.

3.2 Procedures: General Data

Each researcher will collect various forms of data throughout the course of the project. Data collected will be a combination of identifiable and non-identifiable, source or original and transcribed – whatever the data source, it must be managed in accordance with these general principles:

- Before a researcher can access or collect any data, the Trust Research and Development Department, and the relevant Research Ethics Committee must approve the research project in writing.
- Collect only data specifically required for the purposes of the research project.

- Personal data that is provided for health care, or obtained in health services/medical research, must be regarded as confidential.

The Data Protection Act applies to data relating to a living individual who can be identified from the data; or from other data and information where it would be easy to link the individual with the data concerned. There is a statutory obligation to apply an 'audit trail' to any data that comes under the Act. It is considered good practice to apply the same stringent processes to all other types of research data.

- All data must be stored in a safe and secure environment that cannot be accessed by unauthorised persons. This is applicable for the duration of the project and for the specified archive period following completion.
- As a minimum requirement, the: five basic, Eight Data Protection and Six Caldicott principles must be adhered to when collecting information about a research participant (this also applies to staff who may be research participants). These principles are contained in Appendix C.
- Clinical Trials involving 'Investigational Medicinal Products' must be approved by the Medicines and Healthcare products Regulatory Authority (MHRA) and conform
- to the *EU Directive on Clinical Trials* and Good Clinical Practice when collecting, managing and archiving research data

4. Roles and Responsibilities

Core Documents

Chief/Principal Investigators are required to keep, and maintain, a CORE set of documents (see Appendix A) for EACH research project they manage. All core documents should be kept in a designated file called a Site Master File (or local equivalent). These serve to demonstrate good research practice, but do not fall under the requirements of the EU Clinical Trials Directive.

In addition to the above, if a study falls within the jurisdiction of the EU Clinical Trials Directive, then the list of CORE documents (Appendix A) is superseded by a list of ESSENTIAL documents (Appendix B) The researcher then has a statutory requirement to adhere to Good Clinical Practice (GCP) and maintain the essential documents.

Access to Core Documents and Source Data/Documents

Only members of the study team, the appropriate regulatory and inspection bodies and those specified in R&D and ethics approved documentation, have the right to access study data, whether this data is capable of identifying the participant or not.

The researcher may employ only the method of data access and collection specified in the approved project protocol. The R&D Department and the relevant Research Ethics Committee must approve any subsequent amendment, generally in writing.

Under the Research Governance Framework the CI/PI is required to implement procedures to ensure the collection of accurate, high quality data and that the integrity and confidentiality of that data is protected at all times.

Changes or corrections to study data

Any change or correction to study data should be dated, initialled and explained (if necessary) and should not obscure the original entry (i.e. an audit trail should be maintained); this applies to both written and electronic changes or corrections.

Location of study data whilst project in progress

All study data (including identifiable and non-identifiable material) must be kept in a safe and secure location, accessible only by the study team. It is essential that study data is never in a position where confidentiality can be breached, unauthorised access could place, or unauthorised alteration can be made; otherwise data integrity cannot be assured.

4.5 Transferring data to a third party

Data should not be passed to anyone outside of the research team. If data transfer is a requirement of the project, the transfer details must be submitted, and agreed, as part of the project R&D and ethics approval processes. In the case of human tissue leaving the Trust, a Material Transfer Agreement may be required. Please contact the R&D Department for further information and advice.

4.6 Access to identifiable Patient Medical Health Records

If a researcher wishes to access identifiable patient medical health records solely for the purposes of research, prior authorisation must be obtained according to local Trust arrangements. It is not acceptable to access patient records via any other route. The Trust will not release any information unless the project has received both R&D and research ethics committee approval. Any researcher requesting medical health records must either be employed by the Trust; hold an Honorary Trust Contract or R & D Confidentiality Letter AND have patient consent or PIAG²⁴ approval.

4.7 Data held electronically

It is likely that research data will be stored, generated or accessed electronically. In addition to the 'general principles' of data protection and *Appendix 3 of this document*, the following steps should be followed:

Ensure that the correct authorisation has been obtained to access the data;

Do not use someone else's password, or name, to access data.

Encrypt data wherever possible.

It is strongly recommended that researchers use a unique study number for individual participants rather than entering participant identifiable data onto a computer

Password protect documents and databases

Keep computer in a safe and secure environment.

Images required for research purposes must be obtained and kept in accordance with local policy.

Do not send identifiable information through the Internet unless it is via a Trust approved secure system.

²⁴ The Patient Information Advisory Group was established to provide advice on issues of national significance involving the use of patient information and to oversee arrangements created under Section 60 of the Health and Social Care Act 2001. Its membership is drawn from patient groups, healthcare professionals and regulatory bodies. <http://www.advisorybodies.doh.gov.uk/piag/>

Information should be protected by clearly defined and controlled backup as defined by local Trust policies and procedures.

Backups must be held in a secure location with protection from fire and theft.

Management of Source Data

Source Data is defined in ICH/GCP as all information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).

Every research project is different and data will be collected in a variety of ways, including but not limited to: Paper, Audio Tape, Video, and Photographic/Web Camera. It is therefore important to remember that the primary method of collection of any data is the original source i.e. the very FIRST TIME that the data was recorded.

Generally source data consists of original documents such as:

- Medical Health Records and GP Notes
- Clinical charts
- Laboratory notes
- Subjects' diaries
- Visit appointment diaries

Examples of Source Documents

It also includes more specific documents such as:

- Consent forms
- Questionnaires
- Pharmacy dispensing records
- Recorded data from automated instruments, e.g. ECG
- Tapes of interview recordings
- Transcriptions certified after verification as being accurate and complete
- Photographic negatives, microfilm or magnetic media^{9/10}
- X-rays, Scan pictures and reports
- Laboratory Sample Logs, Freezer Books
- General Practitioner Letter/Records
- Laboratory reports and records kept at the laboratories

It should be noted that the above list is not exhaustive, but highlights the types of documents that should be considered as source data if used as part of the data collection process during the study.

Data Archiving Process

The *Research Governance Framework* states that it is the responsibility of the Chief/Principal Investigator to make suitable arrangements for the appropriate archiving of study data.

If the Trust is acting as Sponsor²⁵ all data must be retained for at least 10 years following completion of the project. However, if the project is a clinical trial involving the use of an investigational medicinal product and relates to either an initial marketing, or an amendment to an existing marketing authorisation, then the data must be archived in accordance with ICH-GCP guidelines.

Details of all archiving arrangements must be provided to the R & D Department.

6.1 Pre-archiving points to consider

Archiving retention periods vary depending on the nature of the research project conducted. Therefore, as a general rule the Trust recommend the following - If the study is a clinical trial for either a first Marketing Authorisation, or an amendment to an existing Marketing Authorisation, then data should be held in accordance with ICH-GCP. For all other Trust Sponsored research, data must be retained for TEN Years following completion of the project or 'End of Study'. If, however, another Organisation has the responsibility of acting as Sponsor, archiving should be in accordance with their requirements and/or policies and procedures.

When working with commercial partners it is advisable to discuss data archiving as early as possible during the research process. Due to limited 'Trust' storage space, it is a recommendation that the Chief / Principal Investigator asks the company to arrange off-site archiving of study data at the end of the project.

CI/PI are required to clearly identify the medical records of patients taking part in research projects²⁶. The suggested process for this is to place a sticker on the front/or inside²⁷ cover of the records that denotes: the patient is in a research study and the date the notes will no longer be required for research purposes. If subsequent to this, the patient takes part in another study, and the retention period for this project is after the original date, another sticker, displaying the new date should be placed on top of the old one (the longer time period always taking precedent). It is essential that records for patients involved in research studies or clinical trials are not microfiched, or electronically scanned, in order to preserve them in their original format.

The Chief / Principal Investigator must also inform any other departments involved in the study, of the requirements regarding the source data that should be retained, as well as the retention period.

Study data must remain accessible and available for inspection and auditing purposes to both the Trust and any other recognised regulatory body.

The storage facility must be secure, with appropriate environmental controls and adequate protection from fire, flood and unauthorised access.

Identifiable data must not be archived on the researcher's home premises

6.2 Archiving Process

²⁵ If another body were acting as research sponsor, then it would be normal practice for the Trust to defer to the archiving arrangements made by that organisation

²⁶ This process is classified as an Administrative rather than a Clinical alert

²⁷ The research sticker should be placed either on the front, or inside, cover of the patients notes depending on local Trust policy/procedure

- For electronically held identifiable data, the files should be encrypted prior to archiving. The encrypted files will each have a code, an 'encryption key', which must be stored separately to the electronic data files.
- Compress electronic files to save space, by using an application such as WINZIP. The data should then be saved onto a Compact-disc recordable-read only memory (CD-R²⁸). Small electronic data sets could be stored on floppy disc.
- The 'subject identification key' linking participants to codes must be archived separately to the coded data.
- Put data and documents for archiving in numbered and labelled boxes²⁹ An inventory listing the individual boxes contents should be drafted – place one copy in the corresponding box, and retain a second copy to be held by the CI/PI (to form a log).
- Seal the archiving boxes with tape, and sign across a sealed area.
- Deliver to secure archiving facility³⁰.

6.3 Post Archiving

- The Chief/ Principal Investigator must maintain a log of archived documents, their location and destruction date. These records must remain in the appropriate location even if the member of staff leaves the Trust/ Department. In addition the responsibility of maintaining the log must be passed on to another member of staff.

6.4 Destruction

- The R & D Department must be contacted prior to the disposal of any research documents
- On or soon after the designated destruction date, documents and files containing personal data should be shredded or incinerated.
- The person responsible for shredding or incinerating the documents / electronic records should sign the original archiving log³¹ by to verify that destruction has taken place.

7 Implementation and Monitoring

This procedure will undergo a process of implementation and be subjected to ongoing monitoring in accordance with Trust Policy.

- The Head of Research and Development is charged with the overall responsibility for the implementation and distribution of this procedure. However, specific tasks related to the same can be delegated to other members of the Research and Development Team accordingly.
- A copy of this procedure will be made available to all members of Trust staff who request organisational sponsorship. The Research Governance Coordinator will be charged with promoting awareness of the same, where required, during the governance review process. This document

²⁸ Data integrity is only guaranteed for 5 years on CD-ROM. CD's should be copied after this time period has elapsed

²⁹ The Trust recommends that each box be labelled twice, once on short side and once on long side. The labels should be written in indelible ink and contain the following information: Box number, CI/PI name, Project title and reference number, and date of destruction

³⁰ If being archived off-site, a record must be kept detailing the location and company details

³¹ It is advisable to retain the original archiving log indefinitely as evidence that proper procedure has been followed

can also be found on the departmental website www.rdnottspct.nhs.uk ensuring the widest possible circulation. Further, a written record of employees having received and read this document can be found at appendix 1.

- Awareness raising and training sessions will not be specifically provided for the Data Management in Research procedure. Rather training in 'best practice' generally will form part of the programme of research and governance sessions delivered by the Research & Development, which can be found in the Learning & Development brochure.

The monitoring of the uptake and adherence to this procedure will form part of the Research and Development Department's existing monitoring and audit provision. Any deliberate misuse of research data will be managed via the Research Fraud and Misconduct and Trust Disciplinary Policies.

9. Review and Revision Arrangements

This policy will be reviewed at least once within the maximum-permitted period of three years. However, in accordance with good practice will be reviewed more regularly, in instances where it may be affected by major internal or external changes such as but not limited to:

- Legislation
- Practice change
- Changing methodology
- System/technology change

11. Relevant Legislation/National Guidance

1. [Research Governance Framework for Health and Social Care, second edition, 2005](#);
2. Directive 2001/20/EC - Commonly referred to / cited as the EU Clinical Trials Directive:
http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_121/l_12120010501en00340044.pdf
3. ICH/GCP – International Conference on Harmonisation Guidelines for Good Clinical Practice 1996 -
<http://www.ich.org/cache/compo/276-254-1.html>
4. Freedom of information Act, 2000 - www.hmso.gov.uk/acts/acts2000/20000036.htm
5. Data Protection Act 1998 - <http://www.opsi.gov.uk/acts/acts1998/19980029.htm>
6. Department of Health (2003) [NHS Code of Confidentiality](#):
<http://www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf>

7. Central Office for Research Ethics Committees, Standard Operating Procedures:
<http://www.corec.org.uk/applicants/index.htm#050718a>
8. Human Tissue Act 2004: <http://www.opsi.gov.uk/acts/acts2004/20040030.htm>
9. GMC guidance 'Making and using visual and audio recordings of patients'
10. Individual Trust Policies should be accessed for local arrangements

Core Documents to be retained as a minimum for all research projects

Documents to be maintained	Rationale	Location
Copy of Trust R&D approval letter Copy of the appropriate ethics approval letter. Copies of any amendment approval/acknowledgment letters.	To demonstrate that the correct approval has been given by the R&D Dept and relevant ethics committee	I Site File
Approved protocol, including any amendments.	To ensure that the correct, approved version is being used	Site File
Copy of the approved consent form, information sheet, ward information sheet, GP letter	This ensures that the correct, approved version is being used to inform ward staff of the project, and what it entails the patients GP has been notified	Site File
Copy of the Case Report Forms (CRF's) or data collection proformas in use	the correct, approved version is being used	Site File
Original signed consent forms (give a copy to patient and put a copy in the notes)	to verify that consent has been obtained prior to participation in the study	Site File/ Use separate box file if needed
Creation of a Participant Identification Log, which includes the allocation of a unique study code or number	Provides a confidential list of all study participants who are identifiable by their names, hospital numbers, dates of birth etc, and what their allocated code or study number is (which should be used in lieu of the participants personal identification)	Site File
Completed CRF's, data collection proformas, questionnaires etc– identify by study code or number wherever possible	To demonstrate that relevant data has been collected and recorded for each participant.	Site File/ Use separate box file if needed
Source documents/data -(original documents, data and records e.g. medical records, recorded data from automated machines, blood results, x-rays, pharmacy dispensing records etc, documented medical history)	To document the existence of the participant and substantiate integrity of project data that has been collected	Site File or in relevant dept
List of all study personnel involved in the study, including their signature, initials and study responsibilities.	To identify signatures appearing on study documents Provides a list all persons authorised to make such entries and their project responsibilities.	Site File

Essential Documents required under ICH-GCP Guidelines

Essential documents are documents that individually and collectively permit the evaluation of the conduct of a study and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor and monitor with the standards of Good Clinical Practice. They are also the documents usually audited by the sponsor's independent audit function and inspected by the regulatory authority (ies) as part of the process to confirm the validity of the trial conduct and the integrity of the data collected. *ICH Harmonised Tripartite Guidelines for Good Clinical Practice (1996)*

Title of Document (number donates section to refer to the Guideline document)	Purpose	Located in Files of:	
		Investigator / Sponsor	Institution
8.2.1 Investigator's brochure	To document that relevant and current scientific information about the investigational product has been provided to the investigator	X	X
8.2.2 Signed protocol and amendments, if any, and sample case report form (CRF)	To document investigator and sponsor agreement to the protocol/amendment(s) and CRF	X	X
8.2.3 Information given to trial subject <ul style="list-style-type: none"> ▪ Informed consent form (including all applicable translations) ▪ Any other written information ▪ Advertisement for subject recruitment (if used) 	<ul style="list-style-type: none"> ▪ To document the informed consent ▪ To document that subjects will be given appropriate written information (content and wording) to support their ability to give fully informed consent ▪ To document that recruitment measures are appropriate and not coercive 	X X X	X X X
8.2.4 Financial aspects of the trial	<ul style="list-style-type: none"> ▪ To document the financial agreement between the investigator/institution and the sponsor for the trial 	X	X
8.2.5 Insurance statement (where required)	<ul style="list-style-type: none"> ▪ To document that compensation to subject(s) for trial-related injury will be available 	X	X
8.2.6 Signed agreement between involved parties, e.g.: <ul style="list-style-type: none"> ▪ Investigator/institution and sponsor ▪ Investigator/institution and CRO ▪ Sponsor and CRO ▪ Investigator/institution and authority (where required) 	<ul style="list-style-type: none"> ▪ To document agreements 	X X X	X X X (where needed) X
8.2.7 Dated, documented approval/favourable opinion of institutional review board (IRB) IRB/IEC /independent ethics committee (IEC) of the following: <ul style="list-style-type: none"> ▪ Protocol and any amendments ▪ CRF (if applicable) ▪ Informed consent form(s) ▪ Any other written information to be 	<ul style="list-style-type: none"> ▪ To document that the trial has been subject to review and given approval/favourable opinion. ▪ To identify the version number and date of the document(s). 	X	X

<p>provided to the subject(s)</p> <ul style="list-style-type: none"> ▪ Advertisement for subject recruitment (if used) ▪ Subject compensation ▪ Any other documents given approval/favourable opinion 			
8.2.8 Institutional review board/independent ethics committee composition	<ul style="list-style-type: none"> ▪ To document that the IRB/IEC is constituted in agreement with GCP 	X	X (Where required)
8.2.9 Regulatory authority (ies) authorisation/approval/ notification of protocol (where required)	<ul style="list-style-type: none"> ▪ To document appropriate authorisation/approval/notification by the regulatory authority (ies) has been obtained prior to initiation of the trial in compliance with the applicable regulatory requirement(s) 	X	X (Where required)
8.2.10 Curriculum vitae and/or other relevant documents evidencing qualifications of investigator(s) and sub-investigator(s)	<ul style="list-style-type: none"> ▪ To document qualifications and eligibility to conduct trial and/or provide medical supervision of subjects 	X	X
8.2.11 Normal value (s) / Range (s) for medical/laboratory/technical procedure (s) and/or test (s) included in the protocol	<ul style="list-style-type: none"> ▪ To document normal values and/or ranges of the tests 	X	X
8.2.12 medical/laboratory/technical procedures /tests <ul style="list-style-type: none"> ▪ certification or ▪ accreditation or ▪ established quality control and/or external quality assessment or ▪ other validation (where required) 	<ul style="list-style-type: none"> ▪ To document competence of facility to perform required test(s), and support reliability of results 	X (Where required)	X
8.2.13 Sample of label (s) attached to investigational product container (S)	<ul style="list-style-type: none"> ▪ To document compliance with applicable labelling regulations and appropriateness of instructions provided to the subjects 		X
8.2.14 Instructions for handling of investigational product (s) and trial-related materials (if not included in protocol or Investigator's related materials Brochure)	<ul style="list-style-type: none"> ▪ To document instructions needed to ensure proper storage, packaging, dispensing and disposition of investigational products and trial 	X	X
8.2.15 Shipping records for investigational product (s) and trial-related materials	<ul style="list-style-type: none"> ▪ To document shipment dates, batch numbers and method of shipment of 	X	X

	investigational product(s) and trial-related materials. Allows tracking of product batch, review of shipping conditions, and accountability		
8.2.16 Certificate (s) of analysis of investigational product (s) shipped	<ul style="list-style-type: none"> ▪ To document identity, purity, and strength of investigational product(s) to be used in the trial 		X
8.2.17 Decoding procedures for blinded trials	<ul style="list-style-type: none"> ▪ To document how, in case of an emergency, identity of blinded investigational product can be revealed without breaking the blind for the remaining subjects' treatment 	X	X (third party if applicable)
8.2.18 Master randomisation list	<ul style="list-style-type: none"> ▪ To document method for randomisation of trial population 		X (third party if applicable)
8.2.19 Pre-trial monitoring report	<ul style="list-style-type: none"> ▪ To document that the site is suitable for the trial (may be combined with 8.2.20) 		X
8.2.20 Trial initiation monitoring report	<ul style="list-style-type: none"> ▪ To document that trial procedures were reviewed with the investigator and the investigator's trial staff (may be combined with 8.2.19) 	X	X

Best Practice Principles

Appendix 3

The 5 basic principles of 'Management of Personal Information' are:

- Any personal information given for one purpose must not be used for another purpose without the consent of the individual concerned because that use may breach confidentiality.
- You must not gain access to information you do not need to see or pass information to someone who is not entitled to have it.
- Every member of staff has an obligation to protect confidentiality and a duty to verify the authorisation of another person to ensure information is only passed on to those who have a right to see it.
- The rules are there to protect both the patient and staff from breaches of confidentiality, but they should not be applied so rigidly that they are impractical to follow or detrimental to the care of the individual concerned
- All staff should understand their responsibility to protect the confidential information they collect and use and follow the rules and guidance available to them

Code of Conduct- security and confidentiality of patient and personal information, Nottingham Acute Hospital Partnership ICT Service (2003)

The eight principles of the Data Protection Act (1998) are:

There are 8 data protection principles, which regulate the use of person identifiable data (personal data). Any use of personal data should be:

1. Fair and lawful
2. Used only for specified and lawful purposes
3. Adequate, relevant and not excessive to need
4. Accurate and kept up to date
5. Not kept longer than necessary
6. Processed in accordance with data subject rights, including rights of access
7. Kept secure and protected against accidental disclosure, loss or damage
8. Not transferred outside the EEA.

Data Protection Act (1998)

The six principals of Caldicott are:

1. Justify the purpose for using patient confidential information
2. Only use it when absolutely necessary
3. Use the minimum identifiable information required for that purpose
4. Access should be on a strict need-to-know basis only
5. Everyone must understand their responsibilities to protect information, and
6. Everyone must understand and comply with the law

Code of Conduct- security and confidentiality of patient and personal information, Nottingham Acute Hospital Partnership ICT Service (2003)

Employee Record of Having Read the Policy

APPENDIX 4

Title of Policy/Procedure: **Best Practice Guidance: Data Management in Research**

I have read and understand the principles contained in the named policy.

PRINT FULL NAME	SIGNATURE	DATE

INTELLECTUAL PROPERTY

In its excellent Guide For NHS Researchers on Handling Inventions and Other Intellectual Property (the "Guide"), the NHS Executive notes that 'Intellectual Property' is: *"the novel or previously undescribed tangible output of any intellectual activity...it has an owner it can be bought, sold or licensed and must be adequately protected. It can include inventions, industrial processes, software, data, written work, designs and images"*.

It follows, therefore that 'Intellectual Property Rights' ("IPRs") are *"legally-protected rights which enable owners of items of intellectual property to exert monopoly control over the exploitation of these rights, usually with commercial gain in mind. They give the right to stop others exploiting this property, sometimes for a fixed period, sometimes indefinitely"* (quoted from the Guide).

These legally protected rights can include:

Type of IPR	Description
Patent	Inventions, each embodying a new idea capable of being made or used by industry and involving a non-obvious inventive step.
Copyright	Literary and artistic works, films, videos, records, broadcasts and typographical arrangements, including computer software.
Registered design right	Designs and drawings, mainly of aesthetic objects.
Unregistered design right	Engineering components, architectural drawings, etc.
Trade mark	Product brand names, company logos, etc.
Know-how	Trade secrets, background techniques.

The NHS has (for better or for worse) been charged with the aim of breaking out of the so-called 'break-even' culture. It has realised that one of the best areas of income generation in the NHS is the field of research and development and commercialisation of innovations arising out of such research and development - by obtaining one or more of the protections noted in the table above.

We have mentioned the NHS Executive's Guide. This document sets out a series of 'frequently asked questions' and their respective answers in relation to NHS bodies and their researchers obtaining intellectual property rights arising out of the research undertaken. The Guide can be found at:

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4008102

The Guide includes questions (and answers to those questions) such as:

- What must I do if I think I may have made an invention?
- When should I publish my findings from the research?
- Which categories of intellectual property rights are relevant to NHS research?
- How can protection be achieved for these categories?
- Who decides whether to seek protection or to allow immediate publication?
- When should a patent application be made?
- Will an NHS provider always exercise its right of ownership?
- What if non-NHS employees are engaged in the research?

In addition to the short-form Guide noted above, the Department of Health has published a Framework and Guidance document on the Management of Intellectual Property in the NHS (called "The NHS and an Innovative Organisation") (the "Framework Guide"). This more in-depth Framework Guide can be found here:

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4002660

The Framework Guide provides advice and assistance to NHS organisations on how to work with its employees in excelling in innovation and notes the role of the 'NHS Hub' as the key adviser organisation.

RESEARCH FRAUD AND MISCONDUCT

What is it?

The term **Research Misconduct** can be defined as deviation from accepted ethical practices for proposing, conducting and reporting research³². It recognises there may be reasons other than 'fraud' that the research data may be unreliable.

Research Fraud is a form of scientific misconduct involving deception. It is always deliberate, and is distinguished from honest error.

For the purposes of this document the terms **Research fraud** and **Misconduct** encompass (but are not limited to):

- Fabrication, plagiarism, or deception, in proposing, carrying out, or reporting results of research
- Deliberate, dangerous or negligent deviations from accepted practice in carrying out research
- Failure to follow established protocols with either actual or potential consequences, if the failure results in unreasonable risk or harm to humans, other vertebrates or the environment
- The facilitation of misconduct in research by collusion in, or concealment of such actions by others

It **does not** include honest error or honest differences in the design, execution, interpretation or judgement in evaluating research methods or results or misconduct (including gross misconduct) unrelated to the research process³³.

Both fraud and misconduct involve significant breaches of research integrity that undermine scientific enterprise and public confidence.

Detection

Research Fraud and Misconduct can be detected in a number of ways:

- During the approvals process
- At least 10 % of the projects given Research Governance Approval will be audited by a member of the R & D team, in order to comply with the requirements of the *Research Governance Framework for Health and Social Care (2005)*
- Via Research Ethics Committees
- Via the Trust Incident Reporting system
- Through written, telephone or e-mail complaints

Roles and Responsibilities

The primary responsibility for detecting and preventing scientific misconduct lies with the Chief Investigator for the study and the researcher's employer³⁴.

The NHS expects that all researchers will:

- Take necessary steps to familiarise themselves with available guidance as to 'best practice' in matters relevant to their area of research. This may include research policy, finance and safety.

³² Obispo.S (1996) *Policies and Procedures for the Handling of Allegations of Scientific Fraud and Serious Misconduct*, California Polytechnic State University, California.

³³ Medical Research Council (1997) *MRC Policy and Procedure for Inquiring into Allegations of Scientific Misconduct (Section 2.11)*, MRC, London.

³⁴ Department of Health (2002) *Development of Management and Governance in Primary and Community Care: Information for PCTs Executive Summary*, Department of Health, London.

- Observe such legal and ethical requirements set out by the NHS or other relevant governing bodies involved in their field of research
- Take appropriate steps to ensure the research participants' dignity, rights, safety and well-being
- Report any conflict of interest
- Observe the principles of fairness and equity in the conduct and subsequent publication of their research

FURTHER GUIDANCE

- Mental Capacity Act 2005: <http://www.legislation.gov.uk/ukpga/2005/9/contents>
- The Primary Care Research Network (East Midlands and South Yorkshire): www.pcrn-emsy.org.uk
- Clinical trials toolkit: www.ct-toolkit.ac.uk
- Training: <http://www.crncc.nihr.ac.uk/training>
- Royal College of General Practitioners 'Research Ready Accreditation Scheme': www.extension.rcgp.org.uk/researchready/survey.aspx
- East Midlands Research Design Service: www.rds-eastmidlands.org.uk
- Yorkshire & Humber Research Design Service: <http://www.rds-yh.nihr.ac.uk/>
- National NIHR Portfolio: http://www.crncc.nihr.ac.uk/about_us/processes/portfolio
- DH Research & Development: www.dh.gov.uk/en/Researchanddevelopment/DH_476
- Integrated Research Application System www.myresearchproject.org.uk/
- UK Clinical Research Collaboration: www.ukcrc.org/.

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- Freedom of information Act, 2000: http://www.opsi.gov.uk/acts/acts2000/ukpga_20000036_en_1
- Data Protection Act 1998 - http://www.opsi.gov.uk/acts/acts1998/ukpga_19980029_en_1
- The NHS Confidentiality Code of Practice (2003): http://www.dh.gov.uk/en/Managingyourorganisation/Informationpolicy/PatientConfidentialityAndCaldicottGuardians/DH_4100550
- Central Office for Research Ethics Committees, Standard Operating Procedures: <http://www.nres.npsa.nhs.uk/>
- Human Tissue Act 2004: http://www.opsi.gov.uk/acts/acts2004/ukpga_20040030_en_1
- GMC guidance 'Making and using visual and audio recordings of patients': http://www.gmc-uk.org/guidance/ethical_guidance/making_audiovisual.asp
- Individual Trust Policies should be accessed for local arrangements.