

# Research Ethics and Governance Handbook



2016/17

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# 1. Introduction

The application of a robust ethics structure is an integral part of good research practice. It ensures that research is, firstly, conducted safely and meets agreed principles, standards and codes of practice; and secondly that it produces knowledge that benefits participants and society, and deepens academic understanding of the subject area. To support staff and students and to facilitate high-quality research, this handbook brings together information and resources to help develop and build a working knowledge of research ethics.

Research ethics is an ever-changing field that is informed and shaped by three key factors:

- (i) the innovative processes and outcomes generated by research that push and extend existing boundaries of knowledge and practice;
- (ii) the expectations of professional and statutory bodies;
- (iii) the expectations of the general public and society. Since it is primarily the researcher's<sup>1</sup> responsibility to ensure that they undertake ethical research, it is imperative that working knowledge of research ethics is kept up-to-date and adheres to current University policies and practices,<sup>2</sup> as well as those of relevant professional bodies and funders.

This handbook does not provide an exhaustive set of information. It may well be necessary to augment its contents with advice from your own field. However, you should not conduct research in a way that is inconsistent with the advice in this handbook, or follow any process that conflicts with those described here.

At Northumbria University, no research may begin until the project has received ethics approval; each Faculty has research ethics procedures in place that are overseen by the Faculty Research Ethics Committee. Gaining ethics approval for research projects is the responsibility of the Principal Investigator (PI) or student (undergraduate, postgraduate taught and postgraduate research). Once ethics approval has been given, the PI or student must ensure that the research complies with the approved project design. If, as the research progresses, changes need to be made to the research design, the PI or student will need to apply for approval for the changes before they can be implemented. The procedures apply to all research, including surveys. University Service Departments conducting research should seek ethics approval through one of the Faculty committees.

The Faculty Director of Research Ethics and one other nominated representative per Faculty sit on the University Research Ethics Committee (REC), which oversees research ethics and governance across the University. REC meets at least four times a year and is chaired by the Faculty Associate Pro Vice-Chancellor (Research and Innovation); the Secretary is the Deputy Director (Research) of Research and Business Services.

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<sup>1</sup> "Researcher" refers to any person who conducts research, including but not limited to: as an employee; an independent contractor or consultant; a research student; an undergraduate or postgraduate taught student; a visiting or emeritus member of staff; or a member of staff on a joint clinical or honorary contract. '[Code of Practice for Research: Promoting good practice and preventing misconduct](#)'. UK Research Integrity Office September 2009

<sup>2</sup> The University's Ethics in Research Policy Statement is [here](#).

## 2. Research Practice

### Principles of Good Research Practice

Northumbria University strives to uphold the highest standards of ethical practice in research and academic integrity. Irrespective of the nature and ethical complexity of a research project, staff and students are expected to ensure that their conduct is driven by the ethical imperative of respect, the intent to do no harm and to contribute to society's knowledge and practice through engagement in research that has beneficent intent.

To achieve a high quality research culture, the following key elements are promoted:

- Respect for the dignity, rights, safety and well-being of participants and researchers
- Valuing diversity in society
- Personal and scientific integrity
- Leadership
- Honesty
- Accountability
- Openness
- Clear and supportive management.

To achieve this, and in line with meeting its responsibilities as a sponsor of research (DH Research Governance Framework for Health and Social Care 2<sup>nd</sup> edition 2005), the University is responsible for:

- Compliance with all current employment, equality and diversity, and health and safety legislation
- Demonstrating the existence of clear codes of practice for staff, and mechanisms to monitor and assess compliance
- Ensuring that investigators and other research staff are aware of, understand and comply with appropriate governance frameworks
- Demonstrate systems of continuous professional development of staff at all levels
- Having agreements and systems to identify, protect and exploit intellectual property
- Ensuring that they are able to compensate anyone harmed as a result of negligence on the part of staff, students and others for whom they have liability; and, if they have agreed to do so, to compensate participants for non-negligent harm arising from research
- Having systems in place to detect and address fraud, and other scientific or professional misconduct by staff
- Having systems to process, address and learn lessons from any errors or complaints brought against their employees
- Permitting and assisting in any statutory inspection, audit, or investigation arising from errors or complaints associated with their employees

Further guidance and practice in this area can be found in the UK Research Integrity Office Code of Practice [here](#).

## **Authorship Contribution Principles and Guidelines for Research Publications**

### **Context**

The term 'authorship' has a number of connotations in the academic context (for instance, in relation to intellectual property or copyright). This policy only applies to authorship in terms of the contribution made to publications as outlined in section 2 below.

### **Policy Environment**

Guidelines on what constitutes authorship and appropriate accreditation are accepted as a key part of good research practice. Further information and guidance on good practice can be found in the [UK Research Integrity Office \(UKRIO\) Code of Practice for Research](#) and [RCUK Policy and Guidelines on Governance of Good Research Practice](#).

### **Authorship Principles and Guidelines**

Those involved in authoring research publications are expected to adhere to the principles and guidelines below:

- Responsibility for determining authorship lies with those who carried out the work
- In the absence of discipline-specific or funder criteria, the definition of an author will be those who meet all of 1-3 of the ICMJE criteria below and (in relation to the fourth criterion) understand and be prepared to take public responsibility for the portion of research that they contributed.
  - Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
  - Drafting the work or revising it critically for important intellectual content; AND
  - Final approval of the version to be published; AND
  - Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Researchers should be aware of practices within their own disciplines, and abide by any stipulations laid down by funders or journals. Where different criteria to the ones above are used researchers should be able to clearly explain and robustly justify their criteria to others outside their discipline.

- Authorship should be discussed at an early stage and throughout the project, to agree those to be listed as authors and those whose work will be acknowledged.

The discussion should include consideration of the ordering of author names (practice varies between disciplines). Every author should be able to explain the author sequence.
- No researcher meeting the agreed authorship definition should be excluded.
- No researcher not meeting the agreed authorship definition should be included.
- The following, by themselves, do not normally justify authorship:
  - securing research funding;
  - providing space;
  - collecting research data;
  - managing or supervising researchers involved in a project. Supervisors of research projects should refer to points 1-3 of the authorship definition.
- Where journal and discipline conventions allow, a description or statement of the contribution of each author should be included in the publication.

- The work of those who do not meet the authorship criteria but have contributed or collaborated on the research should be properly acknowledged in the publication. Specifically, where the research has been supported by any funding (e.g. RCUK, industrial partner) this must be acknowledged.
  - Contributions could include technical help, data collection, data analysis, funders, communities, sponsors and advisers. The nature of the contribution (e.g. scientific adviser, collected data) should be specified.
- Other previously published research on which the current research is based must be properly acknowledged.

### **Responsibilities**

The Lead Author is responsible for ensuring that authorship issues are discussed and communicated, and that any changes are notified in a timely manner. Written records of authorship decisions, including written declarations from all authors, should be kept. Where there are co-authors, one individual should be nominated to take this responsibility. The Lead (or designated) author should seek verification from each of the authors that they:

- have reviewed the content of the publication;
- can confirm that their area of expertise is accurate to best of their knowledge;
- agree with, and understand, the author ordering;
- take responsibility for their own contribution.

In the case of an authorship dispute, the lead author should attempt to resolve this informally in the first instance (see below).

### **Dispute Resolution**

Where there are disputes over authorship, it is the responsibility of the institution(s) involved to resolve. The Lead Author will initially seek resolution informally liaising with the parties involved. In the event that the issue cannot be resolved informally (or if the issue involves the Lead Author) the relevant Faculty Associate

Pro Vice-Chancellor (Research and Innovation) will arbitrate in the first instance. Where there is any potential conflict of interest, the matter will be referred to the Chair of Research Ethics Committee, or to the Faculty Associate Pro Vice-Chancellor (Research and Innovation) as appropriate.

*Source: Approved by Research and Innovation Committee: May 2016*

*To be reviewed: July 2018*

### 3. Informed Consent

Informed consent is one of the core ethical principles of conducting research with human participants and with named data. It is embodied in ethics guidelines, including the [ESRC's Research Ethics Framework](#) in which three of its six core principles are:

- Research should be conducted with integrity and transparency
- The rights and dignity of individuals and groups should be respected
- Wherever possible, participation should be voluntary and appropriately informed

Informed consent is regarded as so important because it respects the autonomy of the participants, and because it protects their welfare (the individual being best placed to judge whether something is unduly risky or harmful to them).

There are three main elements to ensuring consent:

1. Adequate appropriate information to make an informed decision.
2. Voluntariness (with no coercion or undue influence).
3. Competence and/or autonomy.

Any process which lacks one or more of these elements is unable to fulfil the principle of informed consent. In situations where the principle of informed consent cannot be fulfilled, a justification for this must be provided. Only in exceptional circumstances will Northumbria University support research that does not maintain the principle of informed consent. Some of the issues which arise for people conducting research, whilst maintaining the principle of informed consent are:

#### *Adequate Information*

There are some forms of research which cannot be conducted without compromising the element of adequate information to make an informed decision. For example, knowledge of the purpose of the study may influence the behaviour of the participant but covert research violates the principles of informed consent and may invade privacy. The British Sociological Association recognises this tension and recommends that as far as possible informed consent should be maintained but that covert methods may be justified in certain circumstances. Further guidance on this issue is available from the British Sociological Association which can be found [here](#) and the [Economic and Social Research Council \(ESRC\)](#).

#### *Voluntariness*

There are two types of influence which could lead to consent being compromised: coercion (use of force or threats) and manipulation (emotional persuasion, withholding or distorting information). However, at times it can be hard to distinguish between these influences and the acceptable rational persuasion of accurate information. The following are issues which could give rise to concern:

- Improper use of the researcher's relationship to gain consent (for example, where the researcher also provides a professional service to the participant).
- Manipulative presentation of the information.
- Use of financial or other incentives or inducements to encourage people to take part in the research.

#### *Competence and/or autonomy*

In order to provide informed consent, potential participants need to have the ability to: understand and retain relevant information; weigh up the information and make a decision without undue influence; and communicate their consent or refusal. The responsibility rests with the researchers to present information in a way that is accessible to potential participants. There are some situations in which this is not possible. Further detailed guidance in this area can be found in Chapters 4, 5 and 6 of this handbook.



### **Informed Consent and Ethnography: Observations**

Ethnography is the study of human behaviour in the natural settings in which people live. An important aspect to ethnographic research is building researcher-participant relationships based on trust. The process of informed consent may therefore be continuous, verbal, and incremental throughout the life of the research.

Consequently, gaining written informed consent for ethnographic research on individuals, communities, groups, and organisations, is often problematic. Although informed consent is preferred, under some circumstances it is either difficult to gain written consent and/or is not conducive to the efficacy of the research. For instance, informed consent might not be possible if:

1. Gaining informed consent would change the behaviour of those being studied and would therefore distort the data;
2. Access to the groups or communities might be prevented if the researcher's aims and methods were known;
3. Large populations might make it difficult to gain written consent (whole villages, for example);
4. Language/literacy difficulties might make written consent impossible.

Ethnographers recognise that there are alternative forms of consent, and these must always be sought where possible. For example, gatekeepers and translators can be used and verbal consent can be captured on video/audio tape.

### **Consultancy Projects**

At the present time, consultancy projects do not require ethical approval. However, if you anticipate the consultancy project will generate bona fide research outputs then ethical approval will be required.

## 4. Adults Lacking Capacity to Consent to Research

### Introduction

There are different laws in each UK country for research that involves adults who lack the capacity to consent to research; the correct law for the UK country in which the research is being undertaken must be adhered to:

- The Mental Capacity Act 2005 covers England and Wales only
- The Adults with Incapacity (Scotland) Act 2000 applies in Scotland
- Separate legislation is expected to be introduced in Northern Ireland following a wide ranging review of mental health and capacity issues

For more information about the Adults with Incapacity (Scotland) Act 2000, [click here](#)

More information about the Mental Capacity Act 2005 is provided below.

### The Mental Capacity Act

The Mental Capacity Act 2005 ('the Act') provides a legal framework for acting, and making decisions, on behalf of individuals who lack the mental capacity to make particular decisions for themselves, or who have capacity and want to make preparations for a time when they may lack capacity in the future. Anyone working with and/or caring for an adult who may lack capacity to make specific decisions must comply with this Act when making decisions or acting on behalf of that person. The same rules apply whether the decisions are life-changing events or everyday matters. The Act sets out who can take decisions, in which situations, and how they go about this. The Act came into force during 2007.

The legal framework provided by the Act is supported by a Code of Practice (the Code).

The Code has statutory force, which means that certain categories of people have a legal duty to have regard to it when working with or caring for adults who may lack capacity to make decisions for themselves. These categories include anyone who is:

- an attorney under a Lasting Power of Attorney (LPA)
- a deputy appointed by the new Court of Protection
- acting as an Independent Mental Capacity Advocate (IMCA)
- carrying out research approved in accordance with the Act
- acting in a professional capacity for, or in relation to, a person who lacks capacity
- being paid for acts for, or in relation to, a person who lacks capacity.

If you wish to conduct research with adults who lack capacity (see below) you must consult the [Act](#) and be guided by the [Code](#).

Research covered by the Act must be approved by an 'appropriate body'. In England, the 'appropriate body' must be a research ethics committee recognised by the Secretary of State. It is important to identify the appropriate body for your proposed research.

## **Key Issues**

Some of the key issues are set out below as a quick guide to help you with the context of the Act and Code.

### **Capacity**

'A person's capacity (or lack of capacity) refers specifically to their capacity to make a particular decision at the time it needs to be made'.

Whenever the term 'a person who lacks capacity' is used, it means

'a person who lacks capacity to make a particular decision or take a particular action for themselves at the time the decision or action needs to be taken.'

This reflects the fact that people may lack capacity to make some decisions for themselves, but will have capacity to make other decisions. For example, they may have capacity to make small decisions about everyday issues such as what to wear or what to eat, but lack capacity to make more complex decisions about financial matters. It also reflects the fact that a person who lacks capacity to make a decision for themselves at a certain time, may be able to make that decision at a later date. This may be because they have an illness or condition that means their capacity changes.

It also reflects the fact that while some people may always lack capacity to make some types of decisions, others may learn new skills that enable them to gain capacity and make decisions for themselves.

### **Definition of Research**

The Act does not have a specific definition for 'research', but uses the Department of Health and National Assembly for Wales's publication, *Research Governance Framework for Health and Social Care*. This is a medically focussed definition which states:

'Research can be defined as the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods.'

Research may:

- provide information that can be applied generally to an illness, disorder or condition
- demonstrate how effective and safe a new treatment is
- add to evidence that one form of treatment works better than another
- add to evidence that one form of treatment is safer than another
- examine wider issues (for example, the factors that affect someone's capacity to make a decision).

It is expected that most of the researchers who ask for their research to be approved under the Act will be medical or social care researchers. However, the Act can cover more than just medical and social care research. It applies to all research that:

- is 'intrusive' (i.e. if a person taking part had capacity, the researcher would need to get their consent to involve them)
- involves people who have an impairment of, or a disturbance in the functioning of, their mind or brain which makes them unable to decide whether or not to agree to take part in the research (i.e. they lack capacity to consent)
- is not a clinical trial covered under the Medicines for Human Use (Clinical Trials) Regulations 2004.

### **Statutory Principles in Relation to Capacity to Consent**

The Act sets out five statutory principles:

1. A person must be assumed to have capacity unless it is established that they lack capacity.
2. A person is not to be treated as unable to make a decision unless all practicable steps to help them to do so have been taken without success.
3. A person is not to be treated as unable to make a decision merely because they make an unwise decision.

4. Any action carried out, or a decision made, under this Act for or on behalf of a person who lacks capacity must be carried out, or made, in their best interests.
5. Before the action is carried out, or the decision is made, regard must be given to whether the purpose for which it is needed can be as effectively achieved in a way that is less restrictive of the person's rights and freedom of action.

Before deciding that someone lacks capacity to make a particular decision, it is important to take all practical and appropriate steps to enable them to make that decision themselves. Clear guidance is provided in the Code and must be adhered to.

### **Assessing Capacity**

Claims that an individual lacks capacity should be supported by evidence to show, *on the balance of probabilities*, that the individual lacks capacity to make a particular decision at the time it needs to be made. To help determine if a person lacks capacity to make particular decisions, the Act sets out a two-stage test of capacity:

**Stage 1:** Does the person have an impairment of, or a disturbance in the functioning of, their mind or brain?

**Stage 2:** Does the impairment or disturbance mean that the person is unable to make a specific decision when they need to?

Assessments of capacity to make a decision should use the two-stage test. Further details are found in the Code about who should do this, but the usual principle is that it should not be a paid professional person unless the prospective participant has no one close to them who is able to do this, or the decision is particularly complex. There is clear guidance in the Code to help identify when this might be necessary and how to identify an appropriate person.

### **People with Fluctuating or Temporary Capacity**

Some people have fluctuating capacity. For example, someone with bipolar disorder may experience a temporary phase which causes them to lack the capacity to make certain decisions.

It may be possible to put off the decision until the person has the capacity to make it.

Guidance on how to support someone with fluctuating or temporary capacity, and who should be involved, is found in the Code.

### **Best Interest**

A key principle of the Act is that any action carried out for, or any decision made on behalf of, a person who lacks capacity, must be carried out, or made, in that person's best interests. There are exceptions to this, including circumstances where a person has made an advance decision to refuse treatment and, in specific circumstances, regarding the involvement in research of a person who lacks capacity (see chapters 5 and 11 of the Code). But otherwise the underpinning principle of the Act is that all acts and decisions should be made in the best interests of the person without capacity.

Wherever possible, the person who lacks capacity to make a decision should be involved in the decision-making process. Their involvement can help to identify the course of events that would be in their best interests.

### **Advance Decision**

People who are aged 18 or over can make an advance decision under the Act if they have the capacity to make the decision. They must say specifically what treatment they want to refuse, and they can cancel or alter their decision – or part of it – at any time while they still have capacity to do so.

## **The Code and Selected Research-Specific Issues**

The following sections explain some of the research-specific issues in Chapter 11 of the Code:

### **Who is responsible for making sure the research meets the Act's requirements?**

Responsibility for meeting the Act's requirements lies with the 'appropriate body', as defined in regulations made by the Secretary of State (for regulations applying in England) or the National Assembly for Wales (for regulations applying in Wales) and the researchers carrying out the research.

### **How can research get approval?**

Research covered by the Act cannot include people who lack capacity to consent to the research, unless it has the approval of 'the appropriate body' and it follows other requirements in the Act. In England, the 'appropriate body' must be a research ethics committee recognised by the Secretary of State.

Research must also meet one (or both) of the following two requirements:

1. The research must have some chance of benefiting the person who lacks capacity. The benefit must be in proportion to any burden caused by taking part.
2. The aim of the research must be to provide knowledge about the cause of, treatment of, or care of people with the same impairing condition – or a similar condition.

If researchers are relying on the second requirement, the Act sets out further requirements that must be met:

- the risk to the person who lacks capacity must be negligible
- there must be no significant interference with the freedom of action or privacy of the person who lacks capacity, and
- nothing must be done to, or in relation to, the person who lacks capacity which is unduly invasive or restrictive

### **What responsibilities do researchers have?**

Before starting the research, the research team must make arrangements to:

- obtain approval for the research from the 'appropriate body'
- get the views of any carers and other relevant people before involving a person who lacks capacity in research
- respect the objections, wishes and feelings of the person, and
- place a greater importance on the person's interests than on those of science and society.

### **Consulting carers or other consultees**

Once it has been established that a person lacks capacity to agree to participate, the researcher must consult with specified people in accordance with section 32 of the Act to determine whether the person should be included in the research.

The researcher should, as a matter of good practice, take reasonable steps to identify a consultee, or consultees, who are involved in the person's care, interested in their welfare and willing to help. Consultees may not be professional or paid care workers. They will probably be a family member, but could be another person.

Researchers must take into account previous wishes and feelings that the person might have expressed about who they would, or would not, like involved in future decisions.

### **What if a person has capacity when the research starts but loses capacity?**

Some people with capacity will agree to take part in research but then lose capacity before the end of the project. In this situation, researchers will be able to continue the research as long as they comply with the conditions set out in the Mental Capacity Act 2005 (Loss of Capacity during Research Project) (England) Regulations 2007.

**What other safeguards does the Act require?**

Even when a consultee agrees that a person can take part in research, the researcher must still consider the person's wishes and feelings. Researchers must not do anything that the person who lacks capacity objects to. They must not do anything that goes against any advance decision to refuse treatment, or any other statement the person has previously made, expressing preferences about their care or treatment. They must assume that the person's interests in this matter are more important than those of science and society.

A researcher must withdraw someone from a project if:

- they indicate in any way that they want to be withdrawn from the project (for example, if they become upset or distressed), or
- any of the Act's requirements are no longer met.

Special arrangements for emergencies and research that includes human tissue are identified in the Code. Any research that involves Human Tissue will also come under the regulations of the Human Tissue Act (2004); see Chapter Five for further guidance on this.

## 5. Children in Research

Clinical research involving children is vital to increase our knowledge of childhood conditions and improve healthcare for children. However, researchers, professionals and parents often feel anxious about asking children to take part in research, for example because of potential risks or burdens.

The Nuffield Council on Bioethics has published a report and a number of resources for researchers to consider how children and young people can ethically be involved in research. You can access these resources [here](#).

## 6. A Guide to the Human Tissue Act and the Use of the Tissue Bank

### What is covered by the Human Tissue Act?

The Human Tissue Act (2004) covers the storage, use and removal of human tissue. It requires that consent must be given for body parts, organs and tissue from the living or deceased to be removed, stored or used for certain specified purposes.

Human tissue is referred to in the Act as “relevant material” (see definition below).

The activities covered by the Act are referred to as “scheduled purposes”. They are divided into two groups, the activities in **bold** are those understood to take place at Northumbria University and for which tissue will be stored in the licensed Tissue Bank.

#### Part 1:

- Anatomical examination
- Determining the cause of death
- Establishing after a person’s death the efficacy of any drug or other treatment administered to that person
- Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person)
- Public display
- Research in connection with disorders, or the functioning, of the human body
- Transplantation

#### Part 2:

- Clinical audit
- Education or training relating to human health
- Performance assessment
- Public health monitoring
- Quality assurance

When planning a project that requires the use of human tissue, consideration must be given to: consent; obtaining ethics approval; and the safe disposal of human tissue. You have a duty to abide by the legislation and ensure that all necessary measures have been taken.

The general rule is that Part 1 activities always require consent. Part 2 activities require consent if the material is from a person who was dead at the time the material was removed, but do not require consent if the material is tissue taken from living individuals.

Any activity not described by a Scheduled Purpose does not fall within the remit of the Act and does not need to be licensed by the Human Tissue Authority (HTA).

#### *Definition of relevant material*

The definition of relevant material in the Human Tissue Act is:



### **Section 53: Relevant material:**

1. In this Act, "relevant material" means material, other than gametes, which consists of or includes human cells.
2. In this Act, references to relevant material from a human body do not include:
  - (a) embryos outside the human body, or
  - (b) hair and nails from the body of a living person.

#### *Categories of relevant material*

The Human Tissue Authority divides potentially relevant material into three categories: Specifically identified relevant material; processed material and bodily waste products.

#### **1. Specifically identified relevant material**

This includes material like bodily organs and tissues, consisting largely or entirely of cells that are clearly identifiable and regarded as such. This category of relevant material includes human bodies, internal organs and tissues, skin and bone; and specifically the following:

- stem cells created inside the human body
- embryonic stem cells
- non blood derived stem cells
- umbilical cord blood stem cells
- bone marrow
- primary human cell cultures

but not:

- cultured cells which have divided outside the human body
- artificially created embryonic stem cells
- cell lines
- extracted DNA
- plasma extracted DNA

#### **2. Processed material**

Where a processed material is generally agreed – as a result of the process – to leave it always either cellular or acellular, then the presumption should be that all examples should be regarded as such. The HTA would rely on the stakeholder's assurance that the process in question had been carried out. Under this category plastinated tissue and plastinated body parts (where the cellular structure is retained by the plastination process) are to be regarded generically as relevant material; while plasma or serum, for example, will be regarded as not relevant. The two latter processed materials, widely produced from blood taken for treatment, are however examples of where 'normal expectations' may well need to be exercised.

#### **3. Bodily waste products (including excretions and secretions)**

Bodily waste is a less well characterised group of material. Nevertheless, the HTA considers it important to provide a framework of guidance. The HTA considers that bodily waste should normally be regarded as relevant material: The Act cannot be denied on this point. The Act's wording is clear and reflects the possibility that even a single cell can be subject to research. While acknowledging the views of stakeholders who have argued for greater individual discretion, it would be inappropriate to encourage people to grant themselves an exemption on the basis of their own interpretation of the Act. However, the HTA may be able to offer nuanced advice in specific instances. There will be cases where a stakeholder believes that material, intended for a scheduled purpose, is actually acellular. In such cases the stakeholder would need to consult the HTA, and we would then refer the case for advice to a members' panel if necessary.

## Regulation

### *What activities require a licence?*

The Human Tissue Authority is established as the regulatory body to license a number of activities set out in the Act. The licensing requirement applies to all establishments whether operating within the NHS, a University NHS or the private or commercial sector. It is unlawful to carry out the following activities without a licence from the HTA:

- Both hospital and coroner's post-mortem examinations
- The removal, use and storage of material, organs or tissue after death (except for whole and part organs for transplantation)
- Anatomical examinations
- Storage of human bodies, body parts or human tissue (but see exceptions below)
- Public display of human tissue.

### *Licensing exemptions – deceased*

- Material more than 100 years' old
- Storage of material which has come from the body of a deceased person is exempted if the licensed activity relates to the body of a person who died before the day on which the Section came into force, or to material which has come from the body of such a person and at least 100 years have elapsed since the date of the person's death.
- Storage of relevant material which has come from the body of a deceased person is exempted from licensing if the person storing it is intending to use it for the purpose of "qualifying research" or for a specific research project for which such ethics approval is pending. "Qualifying research" refers to research which has been ethically approved by an NHS research ethics committee.
- Storage of relevant material which has come from the body of a deceased person, is exempted from licensing if the relevant material:

- (i) has come from premises in respect of which a licence under Section 16 (2) is in force
- (ii) is stored by a person intending to use it for the sole purpose of analysis for a Scheduled Purpose under the Human Tissue Act other than research
- (iii) will be returned to premises in respect of which a licence under Section 16 (2) is in force when the analysis is completed.

### *Licensing exemptions – living or deceased*

The licensing requirements for storage do not include storage which is incidental to transportation. This means that the storage of material while it is being conveyed from one place to another does not need to be licensed. This would normally be a matter of hours or days, rather than a week or longer.

Storage of relevant material is exempt from licensing where the person storing it is intending to use the material for transplantation:

- and the material is an organ or part of an organ (if it is to be used for the same purpose as the entire organ in the human body) or
- the storage is for a period of less than 48 hours

### *Licensing exemptions – living*

Storage of relevant material which has come from the body of a living person is excepted where the person storing it is intending to use it for:

- Determining the cause of death
- Establishing after a person's death the efficacy of any drug or treatment administered to him
- Obtaining information which may be relevant to another person
- Public display
- Clinical audit
- Education or training related to human health
- Performance assessment
- Public health monitoring
- Quality assurance

- Qualifying research, i.e. research which has been ethically approved by an NHS research ethics committee.

### **The Impact of the Act on Particular Activities**

Those carrying out activities that fall within the Human Tissue Act should ensure that they are familiar with the material provided by the Human Tissue Authority. This section sets out the main requirements, regarding consent and licensing, for the principal activities taking place at Northumbria University covered by the Act.

#### *Research*

The main requirements of the Act in relation to research involving human organs or tissues are:

- Consent must be obtained for any storage and use of tissue removed after death for research purposes
- Consent is required for the storage and use of tissue from living individuals for research unless the material has been anonymised, such that the person carrying out the research does not know the identity of the donor (there may still be a link to the donor via a third party), and the research project has been approved by an NHS research ethics committee or approval is pending.

In very exceptional circumstances, such as an extreme public health emergency, the Secretary of State may make Regulations to allow tissue from the living or the dead to be used for research, without consent.

#### *Storage of human material*

The main requirements of the Act in relation to the storage of human material, organs or tissue are:

- Consent is required for the storage of material from a living individual for any Part 1 activity, except where it is anonymised tissue stored for a research project that has research ethics authority approval or approval is pending
- Consent is required for the storage of material from a deceased person for both Part 1 and Part 2 activities
- Storage of material removed from living individuals requires a licence only if it is stored:
  - for future research that does not have ethics approval (tissue banks).
  - for more than 48 hours for the purpose of transplantation (except blood).
- The storage of tissue from a deceased individual requires a licence except where:
  - it is stored for use in a research project that has received approval from a research ethics authority (see above) or approval is pending.
  - it is sent to unlicensed premises for the purpose of analysis (other than research) and will be returned to licensed premises once the analysis is complete.

#### *Analysis of DNA*

It is an offence, throughout the UK, to have human tissue or cells, including hair, nails and gametes, with the intention of analysing its DNA without qualifying consent, subject to the following exceptions:

- where the material is from a living person and is used for Part 2 activities
- where the material is an existing holding and is used for the activities covered by the Act
- in the course of research where the material comes from a living person, the material is anonymised and the research project has been approved by an NHS research ethics committee.

The offence does not apply to exempt material which is:

- material from the body of a person who died at least 100 years before the Act came into force
- an anonymous existing holding

## **Consent**

### *Organs/tissue removed from the living*

The consent requirements of the Act do not apply to the removal of relevant material from the living but only to the removal of relevant material taken from the dead. Consent for removal of relevant material from a living person continues to be dealt with by the common law. This is because the removal of material from living patients is likely to be:

- a part of the patient's treatment (for example, during surgery or taking a blood sample)
- part of a deliberate donation of organs, tissue or cells
- where a healthy person (who may or may not be a patient) participates as part of a research project. The consent gained for participation in such research must also cover any planned removal, subsequent storage and uses of relevant material (as defined in the Act).

Relevant material taken from a person in their lifetime continues to be treated as removed from the living after their death. It is the point at which the material is removed that determines how it is affected by the Act.

### *Storing tissue, including blocks and slides, for scheduled purposes*

The Act does not distinguish between blocks and slides and any other form of human tissue. Whilst it may be desirable for blocks and slides to be taken and kept for clinical audit, teaching or other purposes, it should not be assumed that consent to a post mortem implies consent to removing and keeping blocks and slides.

The implications of a post mortem, including the need to remove organs or tissue for further examination, must be explained to the deceased person's relatives when obtaining consent. It should be made clear that consent to the removal, storage and/or use of organs or tissue for any scheduled purpose is a separate decision from consent to conducting a post mortem examination (whether partial or full).

### *Record-keeping*

NHS Trusts and other establishments should ensure that they have systems in place to maintain proper records and documentation for all tissue and organs they acquire and/or pass on to others.

The Designated Individual named in licences issued by the HTA should ensure that such systems are in place. It is important to be able to track what happens to organs and tissue for health and safety reasons – for example, should an infection occur, resulting in the need to trace people who came into contact with the material. Keeping proper records demonstrates respect for the donation.

The duty to create and maintain proper records lies with the institution where the material is removed from the body, or where the material is identified as surplus to requirements for healthcare purposes and is set aside for a scheduled purpose. Such initial records should include:

- details of who gave consent
- details of what the consent related to, and of any restrictions on use stipulated during the consent process
- the processes to be applied to the tissue
- when and to whom tissue is transferred (if applicable)
- when and how disposal is undertaken (if applicable).

Tissue may be transferred from one place to another many times. So that an audit trail can be maintained, each institution that handles human organs or tissue must have systems that can record:

- when the material was acquired, and from where
- what has been consented to
- the uses to which the material is put whilst in the institution's care and any processes applied to it
- when the material is transferred elsewhere, and to whom.

### *Removal of human tissue and its subsequent use and storage*

Detail needs to be commensurate with the study. Freely given informed consent should be obtained from every subject prior to clinical trial participation. This is defined as:

'A subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.' (see below)

Consent can be obtained by the Principal Investigator or designated person.

Information about the study should be presented to the participants and should include:

- the study title and an invitation to participate
- the purpose of the study and whether the trial involves research
- why the participant has been chosen
- the voluntary nature of participation, including the right to withdraw from the trial at any time without penalty
- the trial procedures to be followed, including all invasive procedures
- those aspects of the trial that are experimental
- the approximate number of participants involved in the trial
- the participants' responsibilities in the study, including the expected duration of their participation in the trial
- the reasonably foreseeable risks or inconveniences to the subject
- the procedure for advising participants in the event of an abnormal test result. It is Northumbria University policy to provide participants with their own individual test results and the relevant normal ranges.
- details of anticipated prorated payments and expenses, if any, for participating in the trial and any other arrangements for payment, including an explanation of how payment may be influenced by duration of participation or completion of diaries etc.
- assurance that record regulations, will not be made publicly available. If the results of the trial are published, the subject's identity will remain confidential
- identifying the subject will remain confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the subject's identity will remain confidential
- the complaints procedure;
- relevant contact details.

The Consent Form for Tissue Removal, Use and Storage can be found in Appendix 3.

## **Storage of Human Tissue**

### *Storage of relevant material taken from the living*

The Human Tissue Act makes it lawful to store relevant material taken from a living person for scheduled purposes, provided consent from an appropriate person is obtained.

Material may be taken from the living in a variety of circumstances, for example:

- in the course of a diagnostic procedure (e.g., blood sample, biopsy)
- in the course of treatment procedures (e.g., the removal of organs or tumours during surgery)
- specifically, for the purposes of research (e.g., a blood sample taken as part of a population screening programme) or
- for transplantation

The Act allows material taken from the living for any reason to be stored (and used) without consent for the following scheduled purposes, on the basis that these are concerned with the general provision of clinical and diagnostic services:

- clinical audit
- education or training relating to human health
- performance assessment
- public health monitoring
- quality assurance.

Consent is required to store tissue from the living for:

- obtaining scientific or medical information about a person which may be relevant to any other person (now or in the future)
- public display.

### *Standard operating procedures for sample drop-off at Northumbria University's Human Tissue Bank*

The following procedures must be followed if you wish to store human tissue at the University's Human Tissue Bank:

1. Send an email to the Human Tissue Bank at least 24 hours in advance to arrange a mutually convenient time for sample drop off
2. Provide a sealable storage box with the study number written on the box and on the lid with permanent pen. If more than one box is required, each box should be labelled with the study number and a number that indicates the total number of boxes being stored, e.g. '1 of 2', '2 of 2' etc.
3. Ensure all samples in the box are labelled with the study storage number and a series number

### *Existing holdings*

It is lawful to store and use for scheduled purposes, without consent, relevant material and the body of a deceased person that was already held in storage for a scheduled purpose on 1 September 2006. However, where the views of the deceased person or of their relatives or friends are known, those views must be respected.

The existing holdings provisions do not apply to the storage and use of bodies or material, which are the subject of an authority under the Anatomy Act 1984 and where the anatomical examination has not been completed by 1 September 2006.

## **Disposal of Human Tissue**

### *Obtained from the Living*

The Act makes it lawful to treat as 'waste' any relevant material which has come from a person who was:

- in the course of receiving medical treatment
- undergoing diagnostic testing or
- participating in research.

It also states that material no longer used, or stored for use, for any scheduled purpose can be dealt with as waste.

Material taken from the living should normally be disposed of by incineration in accordance with current guidelines.

### *Surplus material from tissue samples*

The Act permits disposal as 'waste', material that has come from a body in the course of:

- receiving medical treatment
- undergoing diagnostic research or
- participating in research

and material that:

- has come from a human body and ceases to be used, or stored for use.

It is normal practice to dispose of such material by incineration. This includes:

- tissue fragments trimmed from the tissue sample before it is processed for histology
- the tissue in the sections trimmed from a wax-embedded block before the usable sections are cut
- the unrecoverable bodily material that is washed out of the tissue during its processing into a wax block.

Relatives will expect remains to be disposed of with respect. As a minimum, stored human body parts, organs and tissue should be disposed of separately from other clinical waste.

### *Organs/tissue removed after death*

Tissue and organs should be handled in accordance with any reasonable wishes expressed by relatives or the deceased person, as long as the method of disposal is legal. The time, place and method of disposal should be recorded.

Basic disposal options are cremation or burial. There is usually a funeral or other religious or non-religious ceremony, either arranged by relatives or friends, with the institution's help if requested, or arranged by the institution.

Relatives may want to be reassured about the suitability of any burial or other arrangements the institution makes.

### *Disposal at Northumbria University*

Human Tissue that can be classed as waste (see above) must be disposed of in line with the Clinical Waste guide below and should go through Northumbria University's Clinical Waste Skip located in Ellison Yard. Material in this skip will be incinerated.

The University has contracted out disposal of the following Clinical Waste Groups:

**Group A**

- Identifiable human tissue, blood, animal carcasses and tissue from veterinary centres, hospitals or laboratories
- Soiled surgical dressings, swabs and other similar soiled waste
- Materials from infectious disease cases.

**Group B – in sharps boxes**

- Discarded syringe needles, cartridges, broken glass and any other contaminated disposable sharp instruments or items.

**Group C – in bags**

- Microbiological cultures and potentially infected waste from pathology departments and other clinical or research laboratories

*Use of the yellow Clinical Waste Skip in Ellison Yard*

All material going out to this clinical waste skip should be autoclaved.

Clinical waste should not be mixed with special or hazardous wastes (significantly, chemically contaminated waste should go to the special waste disposal route).

Material going in the clinical waste skip should be in appropriately labelled yellow clinical waste bags or appropriately labelled sharps boxes.

Bags for the clinical waste skip should be:

- Handled wearing gloves
- Double bagged, where appropriate, and tied shut
- No more than 9kg in weight
- Labelled with
  - University post code
  - University name
  - Faculty name
  - Lab number(Labels are available from University Waste Management)
- Free of any items likely to cause a puncture of the bag. Items such as metal blades, glass slides or pipettes, hard plastic pipette tips, wooden sticks should all go into sharps boxes and then be placed in the clinical waste skip (the contractor will refuse to take any skip with loose material in it).



## 7. Guidelines for the use of animals in research at Northumbria University

All UK research councils, most UK medical charities and many professional organisations e.g. *The British Psychological Society* and the *Institute of Biomedical Science* provide their own guidance on the use of animals in research. Underpinning all of these guidelines is the desire to reduce the number of experiments carried out on animals and in particular those defined as protected species under the *Animals Scientific Procedures Act 1986* (Amended 2012) – **ASPA**. The act allows the licensing of experimental and other scientific (regulated) procedures carried out on “protected animals” which may cause pain, suffering, distress or lasting harm to the animal.

### **Protected species include:**

- All living vertebrate animals, excluding man, and any living cephalopod.
- For foetal, larval or embryonic forms the act applies if the mammal, bird or reptile has undergone two thirds of its gestation
- In other cases, protection applies when the animal becomes capable of independent feeding.

### **Regulated procedures Include:**

- Any procedure fitting the category or pain, suffering, distress or harm equivalent to, or higher than, the insertion of a hypodermic needle.
- Dosing, sampling, withholding of food or water are all procedures.

### **Requirements for licencing:**

- Any UK based regulated procedures must be performed in a licensed and designated establishment with a PEL (establishment licence).
- A programme of work involving regulated procedures on protected animals must be authorised by a PPL (project licence).
- Individuals working under the PPL must be authorised by a PIL (personal licence) in order to carry out regulated procedures.

**N.B. Northumbria University is not a designated establishment therefore any regulated procedures must be performed, under full licensing conditions, at an appropriate designated establishment (usually another UK university).**

### **Tissue obtained under Schedule 1:**

- Specified methods can be used for killing animals without the need for PPL/PIL. However, killing must be performed by a “competent person”.
- Often lists of these people, within the University sector, are compiled by an establishment licence holder (see Requirements for licencing above).

If intending to carry out licensed procedures in conjunction with a licensed establishment then as part of the experimental design (including in grant applications) for a study the 3R's must be considered.

### **The 3R's:**

**Replacement** refers to methods which avoid or replace the use of animals defined as 'protected' under ASPA. Examples of replacements include the following

- *in vitro* methodologies
- human volunteers
- animals not protected under ASPA such as insects/invertebrates
- abattoir material.

**Reduction** refers to methods which minimise animal use and reduce the future use of animals. This approach has the purpose of enabling researchers, through **good experimental design**, to produce comparable levels of information from fewer animals or more information from the same number of animals.

**Refinement** refers to improvements to husbandry and procedures which minimise actual or potential pain, suffering, distress or lasting harm to improve animal welfare where the use of animals is unavoidable.

Further information designed to facilitate the 3R's includes:

### **Arrive guidelines:**

Good practice for the reporting of *in vivo* scientific research involving animals is provided at

<https://www.nc3rs.org.uk/arrive-animal-research-reporting-vivo-experiments>

The purpose of these guidelines is to maximize information published whilst minimizing, further and unnecessary studies.

### **Special Considerations**

#### **Genetically altered animals:**

Use or generation of genetically modified animals/breeding of protected species e.g. transgenic mouse models must be licensed under the ASPA. Experiments involving the genetic modification of other species e.g. Insects/invertebrates, excluding the cephalopods, do not require ASPA licensing but should comply with Northumbria University Genetically Modified Organisms (GMO) regulations.

#### **Studies of free living animals:**

Guidance on ecological/field studies can be found at <http://www.nc3rs.org.uk/wildlife-research>

Any **regulated procedures** to be performed, in the field, must be appropriately licensed (see above). However note that ASPA does not apply to the tagging/marketing of an animal for identification purposes as long as it causes no more than momentary pain or distress.

#### **Animal use in contemporary art:**

Arts and Humanities Research Council (AHRC) guidelines follow Research Councils United Kingdom (RCUK) guidelines in that any animal use in which a **procedure** (see above for definition) is undertaken must have appropriate licensing under ASPA (see above).

***Guidance for applicants wishing to carry out studies, at Northumbria, under the University ethical classification system.***

**HIGH** – All use governed by ASPA (full details of experimental design with consideration of 3R's and relevant H.O. licencing details must be supplied (e.g. PPL/PIL numbers).

**MEDIUM** – Commercially obtained animal tissue (Ideally investigator should gain either confirmation of schedule 1 killing or appropriate equivalent); insects/invertebrates including GMO (description of experiments required and must be acceptable under university GMO policy).

**LOW** – Abattoir derived material. Artist materials e.g. commercially obtained fur (and material not subject to ASPA)

**Useful web links**

[\*Animals Scientific Procedures Act 1986\*](#)

[National Centre for the Replacement, Refinement and Reduction of Animals in Research](#)

[Research Councils UK \(RCUK\): Updated RCUK guidance for funding applications involving animal research](#)

## 8. Prevent Duty

The Counter Terrorism and Security Act 2015 places a duty on all universities, including Northumbria, as a relevant higher education body (RHEB) to have due regard to the need to prevent people from being drawn into terrorism. 'People' in this sense is principally staff and students and those who represent the University. The prevent duty guidance for higher education institutions in England and Wales was published by the government in late summer 2015. This document requires universities to review their arrangements to ensure the Prevent Duty is implemented, to be overseen on behalf of government by HEFCE as 'principal regulator' of the University. HEFCE has produced a Monitoring Framework which all registered HEI providers in England are required to satisfy.

As required by HEFC, the University has produced new and reviewed existing policies and arrangements linked to the headline requirements, including the following, which can be accessed here:

- Statement on Academic Freedom and Freedom of Speech
- Prevent Duty Policy Statement
- Visiting and External Speakers and Events Policy

## **9. Sensitive Research Policy**

A link to Northumbria University's Sensitive Research Policy will follow.

## 10. Research Ethics Process

Northumbria University seeks to ensure that ethical standards in research are maintained consistently. Academic faculties and University Service Departments are responsible for ensuring that all students and staff conducting research (including surveys) are aware of the University's ethical standards, and that all research conducted on staff, students and premises adheres to those standards. Ethics training is mandatory for all academic and research staff every three years. Ethical approval for research conducted in service departments and other areas of the University should be routed through one of the Faculty committees.

### **Ethical Risk Levels**

Research activity can be defined in accordance to its perceived level of ethical risk. Northumbria University seeks to ensure that ethical standards are maintained in research by and throughout the University. Faculties, on behalf of the University, are responsible for ensuring all students and staff conducting research, and all research conducted on University staff, students, and premises is in accordance with the University's ethical standards. In order to help you determine the level of ethical risk for your research projects, we have devised a question and answer self-evaluation form to help your assessment and subsequently inform you about the level of ethical review required.

There are 3 levels of ethical risk:

- **High**
- **Medium**
- **Low**

### **High ethical risks**

Does your research involve one or more of the following?

- Medicinal products
- Clinical trial
- Pharmacologically active substances
- Animals, or material derived from animals
- Children or vulnerable adults
- NHS staff, patients, premises or equipment
- Human tissue (e.g. blood or saliva samples)
- Significant concerns around personal safety or physical discomfort beyond normal experience, for the participants or researchers
- Sensitive topics such as trauma, bereavement, drug-use etc
- Data which comes under the Official Secrets Act

If **YES**, then your project has **High** ethical risks.

### **Medium ethical risks**

Does your research involve any one or more of the following?

- Non-vulnerable adults
- Personal data referring to a living individual
- Secondary data not in the public domain
- Environmental issues
- Commercially sensitive information

If **YES**, then your project has **Medium** ethical risks.

### **Low ethical risks**

Does your research involve any of the following?

- the analysis of secondary data which has been previously published
- desk or lab-based research which does not involve collecting data from people (other than pilot data collected solely within the research team).

If **YES**, then your project has **Low** ethical risks.

### **Online Research Ethics and Governance Approval System**

The online system records information about the research undertaken, whilst also collecting more detailed information about any ethical considerations/implications that may arise as a result of the activity.

A new record should be created for each piece of research activity that is undertaken, regardless of the level of scrutiny determined by the risk status system. This will ensure that there is a comprehensive database of the research activity carried out across the University, which will feed into the annual Research Ethics Audit process

The online form will sit alongside the current Faculty Research Ethics Committee (FREC) processes, details of which can be obtained from your FREC secretary.

Access to the system is through the Northumbria website in My Northumbria.

For further information or support, contact Research and Business Services at [ethicssupport@northumbria.ac.uk](mailto:ethicssupport@northumbria.ac.uk)

### **Amending an approved ethics project**

The form to be completed in this circumstance can be found online *here*.

### **NHS-related guidance in relation to Research Ethics Approval**

This section contains NHS-related guidance relating to ethical approval for research within the National Health Service.

### **Clinical Trials**

The Clinical Trials Toolkit provides practical advice to researchers in designing and conducting publicly funded clinical trials in the UK. The site provides information on best practice and outlines the current legal and practical requirements for conducting clinical trials.

For further information and guidance click *here*.

Northumbria University has insurance cover in place relating to Clinical Trials; please refer to appropriate chapter in this handbook.

### **Health Research Authority (HRA)**

For applications to the National Research Institute for Health Research (NIHR) for project based research working with the NHS, applications for HRA approval are made using IRAS which is now a combined Research and Development and Ethics approval form.

For further information, refer to the HRA Approval Programme section of the HRA website.

### **Integrated Research Application System (IRAS)**

This is a single system for applying for Health Research Authority (HRA) permissions and approvals for health and social care / community care research including research with the Ministry of Justice, in the UK. IRAS enables you to enter information about your project once instead of duplicating information in separate application forms and uses filters to ensure that the data collected and collated is appropriate to the type of study, and consequently the permissions and approvals required.

If you are unsure whether you should complete an IRAS form, please check with your supervisor in the first instance and then your Departmental Ethics Lead.

Before submitting to the IRAS system, please follow Northumbria University's approval process for IRAS submission; [click here](#) for further details.

Once internally approved, complete your submission to the NHS Integrated Research Application System [here](#).

### **NHS Research Passport**

This is a national scheme which allows Northumbria University researchers to access the NHS to undertake research projects without having duplicate pre-engagement checks. This is only applicable to those engaged in a research project with the NHS but dependent on the nature of the research undertaken

The responsibility of the researcher to ensure their completed passport application is forwarded to the NHS Trust where they are carrying out the research activity to be validated.

[Click here](#) for further information on criteria, Northumbria's passport application process and additional related links.

### **Recruitment: Call for Participants**

Northumbria University has formed an alliance with Call for Participants which is an international service allowing Northumbria University researchers to recruit participants for their research through a central website as opposed to social media channels and the university mailing lists. It gives researchers at the University a much wider recruitment pool to draw on through a site aimed at and appealing to the general public.

There are a huge variety of research studies on the site actively recruiting participants already from Universities across the globe.

**Please note, ethical approval through Northumbria University's process must be obtained before adding your study to this site.**

More information can be accessed [here](#).

If you have any queries, please contact [ethicssupport@northumbria.ac.uk](mailto:ethicssupport@northumbria.ac.uk)



## 11. Reporting Adverse Events in Research

### What is an adverse event or incident in research?

An incident is an untoward event or omission that could give rise to, or has the potential to produce, unexpected or unwanted effects that could be to the detriment of the safety of research participants, students or staff of Northumbria University.

An incident includes, but is not limited to, breaches of security, violence, physical injury and psychological distress. It includes 'near misses', where an incident had the potential to cause injury, harm or disruption had intervention or evasive action not been taken. Some examples of possible adverse events that may occur within research include:

- An incident involving violence or intimidation during a research interview
- Theft or damage to property during a research activity
- Accidental injury to a research participant or to a student or member of staff during a research activity.

### Why do adverse events/incidents need to be reported?

The reporting of all incidents, however minor, allows Northumbria University to build up a profile of all the risks to staff, students and research participants and can help to develop good practice and create a safer working environment. It is important to ensure that lessons are learned from any events and that the safety of staff, students and participants is maintained.

You should complete a report on any incident, including a near-miss, as soon as possible after the event. This should include clear information about the location, timing and personnel involved in the incident, as well as its nature and impact and any immediate actions taken. A copy of the report should be received by the Faculty Associate Pro Vice-Chancellor (Research and Innovation) in your faculty on behalf of the Faculty Research Ethics Committee as soon as possible.

In the event of an accident or near miss the University's Incident Reporting Policy must be followed. This policy has been developed to detail the standards to be applied following an accident or incident at Northumbria University or involving a member of staff or student away from the University on official business or as part of their studies.

The purpose of accident/incident investigation is to identify the cause of all work related accidents, injuries, near misses, ill health conditions and violence at work incidents in order to prevent or reduce the likelihood of recurrences.

Incidents are also recorded to allow the University to identify any common trends and to measure performance.

Staff are required to report all work related accidents or incidents to their manager or supervisor who will then investigate the circumstances leading to the accident or incident.

An Incident Report form should be completed for all incidents and accidents and forwarded to the University Health & Safety Team. In the event of a serious incident a report should be made by telephone as soon as possible.

The immediate responsibility for managing an incident falls to the most senior person associated with the project available at the time. Wherever possible, the member of staff involved in the incident should complete the [Incident Report Form](#).

*Incidents are graded as follows, and actions taken accordingly. Near misses are to be graded according to the potential severity of the incident.*

**Level 1 Incidents:**

- Result in death or are life-threatening or lead to permanent total disablement that may prevent the person from following his or her normal occupation, or the occupation for which the person is suited by virtue of his/her education, background and abilities
- Cause damage to property or equipment that results in a cost to the University of over £1m
- Attract media attention for more than three days.

**Level 2 Incidents:**

- Result in injury or distress requiring medical attention or more than 3 days' sick leave
- Cause damage to property or equipment that result in a cost to the University of £100k-£1m.

**Level 3 Incidents:**

- Result in injury or distress requiring medical attention or 3 days' sick leave
- Cause damage to property or equipment that results in a cost to the University of £10k-£100k.

**Level 4 Incidents:**

- Result in minor injury or offence requiring less than 3 days' sick leave
- Cause damage to property or equipment that results in a cost to the University of £1k-£10k.

**Level 5 Incidents**

- Result in no, or very minor, injury
- Cause damage to property or equipment that results in a cost to the University of less than £1k.

The Faculty Associate Pro Vice-Chancellor (Research and Innovation) is responsible for ensuring that the incident is graded, and that the Incident Report is passed immediately to the Executive Dean of Faculty and the University Research Support Office. The Research Office will ensure level 1, 2 and 3 incidents will be passed to the Pro Vice Chancellor (PVC) (Research and Innovation), the University Health and Safety Adviser and the Insurance Advisor.

If the research has been approved by an NHS Research Ethics Committee (or other external ethics approval body) the Principal Investigator is also responsible for ensuring that a copy of the Incident Report is sent to the approving committee.

Anyone wishing to make a complaint about the conduct of research, or about University staff or students in relation to research activity, should approach the Faculty Associate Pro Vice-Chancellor (Research and Innovation) in the relevant faculty. The complaint procedure should be on the copy of the consent form that is given to the participant.

## 12. Data Protection

*(This chapter contains relevant sections from Northumbria's Data Protection Policy and [Records Management Framework](#). Any queries should be directed to Northumbria's Records and Information Manager, [Duncan James](#))*

It is the duty of all staff and students undertaking research activities to follow and maintain the highest standards of academic practice when processing information about living individuals (personal data) as part of their research. All processing of personal data must be in compliance with the terms of the Data Protection Act (1998) (hereafter referred to as 'the Act').

The level of impact the Act will have upon a research project will be determined by such factors as the method in which personal data is collected, the content of the information and whether an individual can be identified by it. It also affects how the results of the research can be published when looking at whether or not the output contains anonymised or identifiable information.

Whilst this guide provides general practices to be followed at Northumbria University, research projects sponsored by external funders may be required to follow specific procedures as dictated by the funding body (the full policy contains relevant extracts from a number of funders).

The main principles of the Act affecting researchers are that personal data should only be collected, recorded and processed:

- with the express permission of the individual to which it relates
- for the purposes for which the person gave their permission
- and retained for as long as necessary to execute that purpose.

### **Data Controllers, Data Processors and Student Research**

#### *Data Controllers*

A Data Controller is the person (or organisation) who determines the purpose for which personal data is to be processed and is responsible for ensuring that processing is 'fair and legal'. The data controller is responsible for instructing a data processor on their requirements for processing personal data and must ensure that the processor conforms to these.

The data controller for research will be determined by who the lead organisation is for the research project,

- Northumbria University will be the data controller where the University is the project lead
- There might be joint data controllers where Northumbria University is in equal partnership in leading a project.
- Research funded by and/or undertaken on behalf of a third party will usually identify the third party as the data controller, unless otherwise agreed.

#### *Data Processors*

A data processor is an organisation that processes data on behalf of a data controller and therefore must do so in line with the requirements of the data controller at all times.

- Where partner institutes are contributing to a Northumbria University led project, they are the data processor on behalf of Northumbria University.
- Where research is funded by a third party or the project is led by a third party, Northumbria University is usually the data processor.

### *Student Research*

Students participating on a Northumbria University or third party led projects will be data processors on behalf of the project lead.

Students who undertake their own research requiring the collection of personal data do so because they have determined that they need to collect that data, they have identified what data they need and they have determined how it should be collected (even if they are following recommendations made by their supervisors). Students are therefore the data controller for their own individual research.

The University is responsible for ensuring that students are adequately advised and guided on data protection issues and anyone processing personal data should be aware of the following issues.

### **Using Anonymised Data**

Anonymised data exists when it can no longer be used to identify a living individual either by itself or in conjunction with any other information available to the person possessing that data.

An example of this would be where a researcher creates two lists to manage the 'anonymity' of the data subjects.

- The first list, the "index list," contains a unique reference number next to the names of the participants.
- The second list, the "working list," uses the same reference numbers against each set of data collected.

By themselves, neither list identifies a specific individual, even though they both contain 'personal information' and it is not until they are together and the reference is used that they identify each individual and the details they have submitted.

In this situation, it is important to store the two lists separately so the list containing the names would be locked away from the "working" list.

Data which is truly anonymised and cannot be used to identify a living individual is not affected by the DPA. However, this does not mean that data should be anonymised 'for the sake of it' or that you should dispose of the 'index list' just to forgo data protection responsibilities. The index list is still an important project record and must therefore be retained for as long as the information contained within it still has a legitimate purpose, for example should proof be required that people used in the research were genuine.

### **Using Personal Data**

The use of personal data for research should be limited to include only that information which is legitimately and exclusively required to complete the task for which it is deemed necessary. This requires researchers to clearly define exactly what personal information they require and for what purpose it is to be used, before they begin collecting and processing it. They should not collect any additional information that is not relevant to the project in hand. For example, if their research requires them to compile data relating to someone's race or sexuality, they should clearly state why the information is required. If there is no just reason to collect such information they should not do so.

### **The Requirement for Consent**

The Act states that the processing of personal data should normally only take place where the living individual to whom the data relates has 'freely given' their consent for it to be used having been 'fully informed' (see 'Obtaining Consent', below) as to how the information will be used. This information should be supplied to the data subject in the form of a "fair processing notice" (see below).

Researchers are afforded some exemptions from obtaining consent where they can prove that (within the law) there is substantial public interest in processing the information without first obtaining consent or where it is not possible to obtain consent *and* its use is 'fair and ethical' so that it does not result in the unwarranted prejudice to the rights, freedoms or interests of the data subject. Applying 'substantial public

interest' can be difficult, so it is important to back up its application by including a statement in the project documentation indicating the potential benefits to the public of the research. Approval should also be sought from the University Research Ethics Committee.

Examples of personal data processed without the explicit consent of the data subject include:

- where the information has been collected for a previous research project and the new project is a continuation of or is related to that project. In this situation, consent should be obtained from the original researcher(s) to use the data.
- where the information is already in the public domain and the use of such data is not likely to cause unwarranted prejudice to the rights, freedoms or interests of the data subject.

Examples of **sensitive personal data** processed without the explicit consent of the data subject include:

- medical research carried out by a health professional or by someone with a similar duty of confidentiality;
- analysis of racial/ethnic origins carried out for equal opportunities monitoring;

Advice on whether or not consent is required to process personal data can be provided by the University Records and Information Manager.

### **Obtaining Consent**

'Freely given' and 'fully informed' consent means that the individual gives consent without any undue pressure from the researcher and with full knowledge and understanding. Consent can subsequently be withdrawn.

An individual may agree to provide personal details in order to answer a researcher's questions, but this does not automatically mean that they are happy to have their details published. Similarly, an individual may be happy for their information to be held and used by the University, but may object if they discover the research is being conducted by the University but on behalf of another organisation. This means that it is important to inform them of all aspects of the research project that may affect them.

### **Who Gives Consent?**

#### *Adults*

When collecting information from participants over the age of 18, it should, in most cases, be possible to obtain consent from the individual to whom the data relates. Consent should not be obtained from anyone else (wife, husband, partner, etc.) if the adult is capable of providing it.

#### *Adults Lacking the Capacity to Consent*

It should be assumed that subjects will have the capacity to consent in the first instance. All practical and appropriate steps to enable them to make the decision to participate in your research must be taken.

Before deciding that someone lacks capacity to make a particular decision, certain steps are set out in the Mental Capacity Act 2005 (if the research is taking place in England or Wales) or in the Adults with Incapacity (Scotland) Act 2000 (if the research is taking place in Scotland). See page 5 for more details.

Clear guidance is provided in the [Code of Practice for the Act](#) and must be adhered to. A helpsheet for social scientists, which is applicable to other disciplines too, and which provides helpful definitions of some of the Act's terms, advice and case examples.

If the project does involve collecting information from individuals who are deemed incapable of understanding what is being asked of them or making their own decision to take part (i.e. lacking capacity to give informed consent), it is a legal requirement that explicit approval must be obtained from a research

ethics committee (REC) that is recognised as an 'appropriate body' under the MCA; currently only NHS RECs and the Social Care REC, all of which work to the standards of the National Research Ethics service, possess that recognition. In order to obtain approval, you must be able to demonstrate that you have an understanding of the legal responsibilities placed upon researchers under the Act. Note that these requirements apply:

- to intrusive research, which is defined as any research which would require the participant to give informed consent
- irrespective of the research discipline; for example, such widely varying research studies exploring the development of assistive technology, or art therapy, in residential care homes which included people with dementia, would fall within the provisions of the MCA.

Applications for approval are made through the [Integrated Research Application System \(IRAS\)](#)

### *Persons under the age of 18*

The Act states that collecting personal information from anyone under the age of 18<sup>3</sup> does not always require the consent of parents or guardians if the child is deemed capable of understanding fully what is being asked of them.

There is no set age under the Act as to when someone is 'old enough to understand' so this may need to be assessed on a case by case basis. When someone is deemed old enough to understand what is being asked of them and provide their own consent, parents or guardians are not authorised to give it on their behalf. Where they are not capable of giving consent themselves, parents or guardians must be consulted.

Projects which require the collection of data from persons who are under 18 without the parents' permission or knowledge should make this clear in their proposal when it is submitted to the Ethics Committee - data collection should not proceed without the Committee's approval.

If you are working with persons under 18 in the UK (age limit may differ in other parts of the world), and usually with vulnerable adults, you must have Disclosure & Barring Service (DBS) clearance. DBS replaces the Criminal Records Bureau Check.

Individuals have been screened by means of a certificate (previously known as a 'disclosure') obtained from the DBS. A Disclosure is an impartial and confidential document that details an individual's criminal record and where appropriate, details of those who are banned from working with children. The DBS will carry out a criminal record check for an individual drawing on four primary sources of information:

- Police National Computer (PNC)
- Local Police Force Records
- Department of Health
- Department for Education and Skills

According to the nature of the contact requirements, information will be drawn from the PNC alone or from every source. This defines 'Disclosure' and constitutes a national standard throughout England and Wales.

Further information about Disclosure is available on the University Website [here](#).

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<sup>3</sup> As a rule, Northumbria University states that collecting personal data from anyone under 18 should only be done with the permission of the individual's parents. However, the University recognises that it is not always possible to conduct research with youngsters where they may not wish their parents to know that are taking part (for example, projects involving underage smokers).

## Fair Processing Notice

A 'fair processing notice' is used to explain clearly to participants the aims of the research project they have been asked to take part in and states the manner in which the information they supply is to be used. The notice will include such information as:

- **Name and contact details for the Data Controller** This will usually be either:
  - The name of the student conducting the research where they are the data controller
  - Northumbria University for research projects where the University is the lead
  - The name of the project funder
  - In some cases, it may be prudent to put that the information is being collected by Northumbria University on behalf of x' (where x is the name of funding organisation) and the contact details for both organisations.
- **A brief but clear description of the projects aims and objectives** so that the individual can decide if it is something they are happy to support.
- **A clear description of what information will be required** from the subject and how it applies to the project
- **A clear description of the project output** and how the information will be presented – anonymised, published on the web, etc.
- **A statement outlining how the collected information is to be managed** - Is the identifiable information to be passed to the funding body upon completion of the project
- **A statement outlining the individual's rights under the Act** should also be included including the fact that they may withdraw their permission, or ask to access the information - within a reasonable time period - who to contact and how (name of data controller).
- **A statement as to how confidentiality will be maintained where it has been promised.**

How the fair processing notice is presented to the individual will depend upon how the information is collected, for example, it may be that the project is conducting entirely web based methods and it is appropriate for the notice to appear on the first web page before the individual proceeds to complete the survey or questions. If the researcher is meeting the individual face to face, they may present a laminated copy of the notice and ask them to read through it before they begin. Telephone researchers may wish to send a copy out in advance of making the call or they may wish to read the notice to the individual at the beginning of the conversation.

## Recording Consent

Recording consent provided by an individual will also be dependent upon the media by which the data is being collected.

Web based collection may be recorded by (but not limited to) methods such as ticking an acceptance box before clicking 'submit,' or by emailing their acceptance. Telephone or other oral methods of collection may involve the data subject speaking their consent onto a recording.

Written consent can be recorded using a signed consent form and stored securely by the researcher along with other project documentation. Examples and template consent forms can be found within individual Faculty guidance and in Appendix 1 of this Handbook. Explicit consent must be established when dealing with sensitive personal data.

### **Disclosure of Personal Data**

Personal data must not be disclosed to any third party individual without the consent of the individual. A third party is anyone who is not the data subject or those permitted to process the data. Only the researcher(s) working with the data should be accessing it.

Individuals who provide personal data may at a later date ask an organisation for access to the information they have provided. In order to do this, they must submit a 'subject access request' to the University. The University will then have 40 days to provide the information.

Individuals also have the right to withdraw their consent to the University processing their personal data. If consent is withdrawn, processing must stop within 15 days of the withdrawal and confirmation that this is the case should be sent to them.

### **Publishing Personal Data**

If the research requires the publication of personal data, this must be done in accordance with the method described when consent was provided by the individuals. For example, if consent was provided on the basis that personal data would be anonymised or that it would not be published on the internet, neither is permitted. Because of this, it is important to provide data subjects with comprehensive information when they are deciding whether or not to provide consent.

### **Internet Based Research**

Internet based research (often referred to as Internet-Mediated Research) is an ever changing means of conducting research through existing and emerging web based technologies, each with their own unique advantages and disadvantages. Internet research may range from simple online surveys delivered via platforms such as the University 'Bristol Online Survey' system, to in-depth and large scale data mining of material already posted online across blogs, discussion fora or social media sites, or through inviting proactive participation through such sites.

Because researchers and participants rarely meet face to face when conducting internet based research, it is often to gauge where individuals are giving free and informed consent to take part in research. Consideration must always be given to how to establish the participants are old enough, competent enough to freely give their own consent (i.e. someone isn't giving it on their behalf).

Things to consider when utilising online research include:

#### *Selecting the Platform*

Researchers inviting participants to partake in their online research have an obligation to ensure that the platform they are using is appropriate and adequately secure enough to ensure that the privacy rights of the participants are met. When selecting the platform, researchers should consider, but not limited to, the following:

- The sensitivity of the data they are collecting – higher risk means more secure!
- The nature of their research and what method of collection is appropriate – survey or social media?
- Where is the system hosted? USA takes personal data beyond the European Economic Area and may therefore breach the Data Protection Act.
- How long the system stores data for – can data be deleted at the end of a project or is it archived on a server somewhere?
- Will participants need to log in and if so, how?
- Can individual requests to delete data be processed?
- How will the processing notification be published?
- Does the system have the capability to record the correct level of consent?



### *Recruitment*

The lack of face to face meeting between researcher and participant can create issues with the recruitment and verification of the identity of participants. In low risk research projects this may not be considered an issue, but in high risk (sensitive) projects there may be a requirement to authenticate individuals “offline” through direct contact away from the main research platform.

With some online forums, individuals may use ‘avatars’ to create their online identity without providing actual names or images of themselves. In these circumstances the avatar might not appear to be ‘personal data’ but in many cases the use of these can still be linked back to identifiable individuals. So the same consideration should be given as is the avatar was the individual’s personal data.

### *Recording Consent*

Online consent, and the way in which it should be recorded should be proportional to the risk to research to participants. For example, recording consent for ‘lower risk’ projects might be sufficiently gathered by an individual ticking an online box to say that they accept the terms of participation, whilst ‘higher risk’ projects which require sensitive personal data may require individuals to complete and return separate consent forms.

In some forums consent may be evidenced via other “implied” means, such as an individual’s active participation in a restricted group or through the completion and submission of an online survey, where the survey included a preamble about the purpose of the research and who is conducting it. It may be waived altogether (in the case of data which is truly in the “public domain” *see below*).

Where the participants are considered minors requiring parental consent to participate, it may be prudent to garner consent ‘offline’.

### *Withdrawing Consent*

As with any research, participants may withdraw their consent at any time during the project. Withdrawal may be as simple as declaring that they no longer wish to participate or they may ask for the information already provided to be deleted.

It is therefore important to know who the chosen system will facilitate such requests – how can you completely delete individual content? How long will content be stored for on the server once it has been “deleted” from the site etc.?

### *Public Domain or Private*

Research that involves mining an existing source such as posts already made on social media or a blogging site should not assume that it’s presence on that site means that it is in ‘the public domain’ and can be used without consent of the contributor. For example, one individual may post on a page or group within Facebook but consider their post “private” because it is only accessible to Facebook members or members of that particular group, whilst another may consider it public because Facebook, or the particular group has so many members. If possible, researchers may wish to direct message individuals to seek their consent to use their post as part of their research.

### *Copyright*

Researchers gathering data, particularly images, from social media must check with the social network provider or site owner to ensure that they have permission to use their content. In most cases, Social media networks will claim copyright alongside the original poster meaning that there may be limitations on the permitted use of the material.

For further information about Internet based research the British Psychological Society have produced the useful ‘Ethics Guidelines for Internet Mediated Research’ which is available [here](#). The Association of Internet Researchers also gives guidance on this topic which is available [here](#).

## **Guidance for the Use of Mobile Devices for Audio and Visual Recording**

Northumbria University takes Information Security very seriously. We invest significant resources to provide students with appropriate systems that they have appropriate tools to conduct their research and to ensure data is protected.

Occasionally however, you may find that you are required to use a personal smart phone or other mobile devices that sit outside of the University and its 'IT Regulations' to undertake audio or visual recordings. As a representative of the University, you are required to ensure that where such devices are used, they are used in an appropriate manner that ensures an equivalent level of security as if they were subject to the University IT regulations.

This guidance covers the use of smart phones and other devices ('device') by students to collect and store information, including audio/visual recordings, for the purpose of conducting research.

Anyone wishing to use a device to gather data may do so, but they must ensure that they do so in line with the following guidance.

### **Device Security**

It is the device owner's responsibility to understand the security features provided by the smart phone/device and to ensure that they are used sufficiently to keep data secure. This includes:

1. Ensuring that the device has installed and configured a tracking and/or remote wiping service (e.g. 'Where's My Droid' for android devices, 'Find My Phone' for windows devices or 'Find My iPhone' for iPhones)
2. Ensuring that the device has up-to-date anti-virus software installed and that it does not block the use of the above.
3. Ensuring that the device 'software updates' service is installed and active to ensure that the latest versions of points 1 & 2 are installed at all times
4. Ensuring that the device includes an automatic locking mechanism which requires a PIN, Password and automatic lock to help protect the device when not in use.
5. Where personal data (as defined by the Data Protection Act 1998) or confidential information is being collected, automatic saving of the device content to personal cloud services is disabled.
6. Automatic syncing with any other personal device is disabled.
7. Information stored on the device is transferred onto your University account at the earliest opportunity and then deleted from the device itself.
8. You do not take a device containing any sensitive information to a anywhere that would be considered a 'high risk' environment (e.g. clubs or pubs where phones are at risk of being lost or stolen)
9. The device is wiped and returned to the 'manufactures settings' prior to disposal – including where it is sold or exchanged.

### **Loss or theft of your Device**

In the unfortunate event that your device is lost or stolen you must:

- Report the loss to the police and obtain a crime reference number.
- Use the remote wiping service to ensure that any data held on there is removed.
- Report the theft to your service provider so that they can also take preventative action against the phone being accessed
- Notify your Faculty immediately, or at the earliest opportunity of the loss (i.e. next working day if lost at night) and assist them with any investigation, should one be necessary.

### **Monitoring of your Device**

The University cannot actively monitor the content of your personal devices, so the onus is on you to ensure the privacy, integrity and confidentiality of any data you store on them.

## 13. Secure Storage of Data

Clear and accurate records enable researchers to demonstrate the procedures and good practice followed and strengthens the reliability of their research. They can protect researchers against allegations of misconduct, show good ethical practice or legal compliance and ensure protection against intellectual theft.

This section outlines the requirements for good records management practices in research projects conducted by staff and students at Northumbria University. Research funded by an external agent may require researchers to follow external practices dictated by the funding party.

### **Which records are retained?**

Researchers are expected to maintain clear and accurate 'whole life' records of all the work they undertake. Records include, but are not limited to:

- Project proposals and applications for funding (including rejected)
- Evidence of any revision to original project proposals
- Project administration and management information (including staffing records, invoices, timesheets and claims etc.)
- Details of the procedures followed, risk assessments undertaken, ethics approvals
- Participant consent forms, primary data generated or collected (recordings, transcripts, databases, photographs etc.) and interim results
- Final outcomes and presentation of results (including organising any promotional events, cost of publishing etc.).

### **Responsibility**

It is the responsibility of the Principal Investigator on any project to ensure that accurate records are maintained and securely stored for the duration of the project. This includes:

- identifying where the project is subject to the provisions of the Data Protection Act 1998 and the requirements therein. See: *Data Protection and Research Records*
- identifying how information will be collected and stored (what format below)
- using the University retention schedule (or the requirements of the project funder) to identify where information is to be retained beyond the final project output date and checking to make sure that appropriate action is taken. See: *Research Records Retention Schedule or the funding bodies requirements*

The Principal Investigator must also ensure that where there is staff involvement on the project, whether in a support or direct involvement, responsibilities are clearly defined and documented.

### **What format should be used?**

Where possible, records should be created and stored electronically. However, the format will depend on the nature of the record itself and the reason for its existence. For example, if the record is an interview with a test subject in which personal data is shared, it could be created as an electronic sound file or as a set of hand written notes.

If the intention is to keep these in their "original" format for the duration of the project, then the storage solution could be to either copy electronic sound files to the network drive or store handwritten notes in a filing cabinet\* It might also be feasible to scan the handwritten notes and store them as electronic files.

If, however, the intention is to electronically transcribe the recorded conversation or type up the hand written notes immediately before disposing of the originals, the long-term storage solution resorts to the storage of the completed transcripts whilst also ensuring the secure disposal of the originals. The method of

storage will also be determined by the content of the record. Records containing sensitive personal data or commercially sensitive information will naturally require more secure methods of storage than those which do not.

### **How records should be stored**

Once the Principal Investigator has determined the format in which the record will be created (based upon the likely format and content), the decision on how it will be stored can be taken. Records should be stored in a manner which is “appropriate” and takes into account the balance between the need for practical access to the record with any requirement to maintain it. It should remain secure through controlled access or regular backup.

Records should be stored in a manner that identifies the content of the record quickly and easily. The same rules should be applied whether the records are stored in hard or electronic copies.

‘Hard copy’ records such as paper documents, tapes, photographs or removable media (memory sticks, disks etc.) should be stored and indexed in appropriate secure containers such as lockable filing cabinets, draws or shelves. Longer retention periods may require this information to be sent to the University offsite storage provider after the project completion.

‘Electronic records’ should be stored in logical files structures and indexed using logical file naming conventions and appropriate security measures.

### **What are “appropriate” security measures?**

There is no single solution for secure storage of project records. Projects that involve the collection of sensitive personal data or commercially sensitive information will require more secure storage than those that do not.

The following are “appropriate”, but not definitive, recommendations for securely storing records:

Projects storing records containing ‘sensitive’ or identifiable personal data as hard copy materials need to make sure that they are stored in a manner that will prevent unauthorised access. This can be achieved through simple measures such as:

- Locking them away in a filing cabinet or
- Ensuring that they are stored in a lockable room.

Assuming everyone remembers to lock the cabinet/room, access should be restricted to authorised members of staff. The extent and degree of security required is closely linked to the nature and sensitivity of the data, the risk from accidental loss, damage or theft, the damage that might arise from its loss and the number of potentially affected individuals. The more sensitive or risky the material the stronger the security arrangements required.

Where personal or sensitive data is held on a computer, there are a number of ways in which files can be protected. These can be as simple as:

- Applying a password to the record or the parent folder
- Limiting access to the storage area – i.e. setting permissions to allow only key individuals to see or open the folder/record
- Remembering to “lock” the PC when leaving the room – i.e. pressing “Ctrl, Alt and Delete” and selecting “Lock Computer”
- Making sure the information is backed up. If the backup is stored locally on CD, DVD or memory stick, remember to keep the device locked away securely. Data held on a removable device should be encrypted.

### **Collecting or removing information from the University**

The management of records extends beyond the confines of the University campus. If there is a requirement to remove or collect data to or from an external site, care must be taken to protect the information. The appropriate action will be dependent upon the content and physical medium in which the information is stored.

The following are “appropriate” but not definitive recommendations for securely managing records offsite:

- Never take original material off site. Take a duplicate (even hard copy) so that if the information is lost or stolen, the original is still available.
- If collecting the information offsite, take care transfer it to the University at the earliest opportunity.
- Never leave any records unattended.
- Ensure that any personal information taken off site is anonymised. If it is lost or stolen, anyone looking at the information should not be able to identify the subjects.
- Think about the suitability of the surroundings before working. For example, if working on a train or in other public areas, do not “spread papers out” so they can be read by the person next to you.
- Where records are being collected by post (for example responses to surveys) the return envelope should be clearly marked with the University logo and marked as ‘Confidential’.

### **What happens to the records when the project ends?**

At the end of the project, the Principal Investigator must ensure that the records are either disposed of securely or, where required, retained in accordance with the retention schedule of either the project funder or the University. See: *Research Records Retention*

Arrangements for the archiving of electronic materials should be made within the Faculty. Hard copy records can be sent to the University’s offsite storage facility. There is no requirement to retain multiple copies of the same record.

A record of archived material should be retained centrally within the faculty together with a clear indication of the length of retention. Authorised and certified destruction will then be arranged at the appropriate time.

### **University guidance on Data Retention**

The University Retention schedule documents the minimum retention periods for Northumbria University research records.

Retention periods are independent of format and therefore can be applied to any medium whether paper or electronic. Retention periods in this document are defined as the ‘Minimum’, which mean that files may be retained for a longer period should they be required but must not be disposed of before the identified time.

Research projects sponsored by external funders may be required to follow the retention practices of the sponsor rather than those outlined in this schedule.

The research section of the University retention schedule can be found on the University website [here](#).

The University Research Data Management Policy can be found [here](#) and additional guidance and resources can be accessed [here](#).

For further information and advice please contact the Records and Information Manager,  
[duncan.james@northumbria.ac.uk](mailto:duncan.james@northumbria.ac.uk)

## 14. Insurance Cover in Relation to Research

The University has a responsibility to protect staff and students and participants involved in research.

In general terms, the University has a package of insurance products to protect staff and students where they are legally liable for a loss due to a negligent act, error or omission.

More specifically, the University has in place Clinical Trials coverage (Legal Liability or No Fault Cover), to respond to claims from research participants enlisted to a clinical trial.

However, the following areas are **EXCLUDED**:

### **Clinical trials involving:**

- Investigating / participating in methods of contraception
- Assisting with or altering the process of conception
- The use of drugs
- The use of surgery (other than biopsy)
- Genetic engineering
- Subjects under age 5
- Subjects known to be pregnant
- Pharmaceutical product /appliance designed/manufactured by the University
- Work outside the UK

### **Limitations apply to:**

#### **Involvement with aircraft:**

Activity with aircraft, aero spatial devices, unaccompanied Airborne Vehicles (drones)

#### **Water craft:**

Boats (other than notified via Campus Services Sport), hovercraft, waterborne craft

Any research, trial or investigation involving the above needs to be notified to the Insurance Advisor to see if insurance can be arranged.

The University Insurance Advisor will liaise with UM Association Ltd (the University's cover provider) as necessary.

The Research Ethics Committee requires that:

1. All project proposals submitted for ethics approval within each faculty, that satisfy the definition of a clinical trial, are sent electronically (including any supporting documentations such as REC form, consent form, information forms etc.) by the Secretary to Faculty Research Ethics Committee to:  
**The University's Insurance Advisor**, Anne Hudson, email [fi.insurance@northumbria.ac.uk](mailto:fi.insurance@northumbria.ac.uk) and copied to: Ruth Hattam, [ruth.hattam@northumbria.ac.uk](mailto:ruth.hattam@northumbria.ac.uk) **Deputy Director, Research and Business Services**
2. Ethics approval for a project from the Faculty is dependent on evidence that adequate insurance cover is in place.

## 15. Legal Agreements

There are various legal contracts that will need to be in place during the lifetime of a research project. The main ones are funding contracts, collaboration agreements, and contract research contracts.

All contracts relating to research are dealt with by the Legal Services Team within the Vice-Chancellors Department and Research and Business Services will work with Principal Investigators to ensure that Legal Services are instructed in respect to contractual arrangements.

Principal Investigators do not have authority under the University's Financial Regulations to sign and enter into contracts on behalf of the University, hence ALL contracts must be reviewed by Legal Services and once finalised, Legal Services will arrange for an authorised signatory within the appropriate Faculty to approve and sign off the contract.

From a research governance perspective, specific reference has been given to the following types of contracts and the process for each that must be followed:

### **Student Placement /Student Project Non-Disclosure Agreements**

The purpose of the Non-Disclosure Agreement ('NDA' – sometimes also referred to as confidentiality agreement) on a student placement or student project is primarily for the protection of the placement/project provider to allow it to confidently expose the student to confidential information about its business.

This may also improve the quality of the placement or project and the learning experience for the student if he/she is not restricted from exposure to confidential information.

The Faculty may issue the NDA document (after completing outstanding details e.g. placement provider and student names and addresses) to the placement or project provider and student. The Faculty should also normally arrange for all the necessary signatures to be obtained. Ideally three identical copies should be signed by all the parties in order that each may retain an original version signed by all. No negotiations or substantive changes must be carried out without the involvement of Legal Services.

Template agreements and guidance notes can be accessed from [here](#).

### **Material Transfer Agreements**

Material Transfer Agreements (MTAs) govern the transfer of one or more materials from the owner (or authorised licensee) ('the provider') to a third party ('the recipient') who may wish to use the material for research purposes. Materials can include cultures, cell lines, plasmids, nucleotides, proteins, bacteria, transgenic animals, pharmaceuticals, other chemicals, alloys and other materials with scientific or commercial value.

Most commercial organisations, and an increasing number of academic institutions, will only release materials if there is an MTA in place between the provider and the recipient. For the provider, this agreement provides control over the distribution of the material, enables them to restrict the use of the material to non-commercial research, and reduces the legal liability of the provider for the recipient's use of the material. In addition, the terms of the MTA can help the provider to gain access to the results of the research, both for information purposes and for commercial exploitation.



**Current Procedure**

Legal Services is responsible for approving and negotiating terms for both incoming and outgoing MTAs, on behalf of Northumbria University. The MTA must be signed by an authorised signatory in the Faculty in accordance with the University's Financial Regulations.

It is important that Legal Services reviews all MTAs to make sure that Northumbria University does not agree to terms that may be in conflict with the provisions of research grants, fellowships, consultancies etc. Among the important issues to be negotiated are publication rights, Intellectual Property (IP) rights, governing law, warranties and indemnities.

For further information, please contact [Deborah Wise](#) or [Katrina Hopkin](#) in Legal Services.

## 16. Guidelines for the Treatment of Intellectual Property

The University has a policy on intellectual property which can be found [here](#). Any queries should be directed to Hugh Rhodes, [hugh.rhodes@northumbria.ac.uk](mailto:hugh.rhodes@northumbria.ac.uk), Research and Business Services.

## 17. Health and Safety

### Introduction

The Board of Governors has ultimate responsibility for the health and safety of staff, students and other individuals while they are on the institution's premises and in other places where they might be affected by its operations. Health and Safety is a core management function and University managers are responsible for ensuring that the Health & Safety policy and associated codes of practice are communicated effectively and that staff and students are competent to fulfil their health and safety roles.

The primary responsibility for implementing the Health & Safety Policy lies with the Vice-Chancellor, assisted by University Executive and senior managers. The effective delivery of this Policy also requires everyone accepting a personal responsibility for their own health and safety and that of others and the provision of professional and competent support and advice to all areas of the University. The University's aim is to achieve best practice in health and safety through continual improvement and the control of risk whilst ensuring the University achieves its vision to be a research-rich, business-focused, professional University with a global reputation for academic excellence.

Health and safety legislation applies just as much to research as it does to any other area of industry. Despite the inherent elements of uncertainty, it is possible for research workers to innovate without exposing themselves or others to unnecessary health and safety related risks

All researchers must:

- take responsibility for their own health and safety and ensure that they don't compromise the health and safety of others by the things they do or fail to do
- work safely and efficiently
- follow the Health & Safety policy, guidance and safe systems of work
- attend training and put it into practice in the workplace
- use protective equipment as recommended
- not change research or other work protocols without first discussing the change with their manager and specialist safety advisers as appropriate
- report incidents that have resulted in, or could have resulted in, injury or damage
- assist in the investigation of accidents with the aim of introducing preventative measures
- report unsafe conditions or actions
- work co-operatively to improve health and safety standards and performance.

It is important that when considering a research project that all health safety and welfare issues are considered at the planning stage and that the appropriate risk assessment is completed and approved taking into account all significant risks to health and safety.

To report an ethical incident not covered by the University or Faculty Health and Safety policy, complete the form which can be found [here](#).

Further information is available at [this link](#).

For support for the mental health and well-being of researchers who have been negatively affected as a consequence of conducting research with groups of vulnerable people, refer to Health and Safety guidance [here](#).

## **18. Misconduct in Research Policy and Procedure**

The current policy can be found on the staff intranet [here](#).

## **19. Research Ethics Audit**

The University's Research Ethics Audit is a qualitative audit that examines the research ethics practices which are applied to staff and Post Graduate Research (PGR) student research projects, and undergraduate and Post Graduate Taught (PGT) student research projects in each academic faculty. The audit is a learning process and through checking a sample of research projects enables each faculty to identify areas of good practice, which may be shared with other faculties and to identify any systemic issues that need to be addressed by either the faculty or the University.

The annual ethics audit is a triennial exercise with themed audits taking place in each of the intervening years. The Research and Ethics Committee approve the themes for audits which are normally conducted between June and September.

## 20. Ethics Guidelines from Professional Bodies and Subject Groups

**The British Educational Research Association (BERA)** is the society for educational research in the UK. It supports educational research through publications, training and development of researchers.

**British Psychological Society** has a Code of Ethics and Conduct and provides ethical guidelines for psychologists.

**The British Sociological Association** has a Statement of Ethical Practice which will be of interest to staff and students working within the social sciences.

**Designing with people** is a website created by the Helen Hamlyn Centre for Design at the Royal College of Art that covers a number of issues about how to design with people, including developing protocols for ethical practice.

**ESRC Research Ethics Framework** sets out what the ESRC requires by way of ethics approval. It is mandatory for ESRC-funded research and recommended good practice.

**The Home Office** provides a concise overview of the legislation about the use of animals in research and the licenses required to undertake research involving animals.

**The Human Genetics Commission** is the UK Government's advisory body on new developments in human genetics and how they impact on individual lives

**The Institute of Biomedical Science (IBMS)** is the professional body for biomedical scientists in the UK. It aims to promote and develop biomedical science and its practitioners. The Institute was founded in 1912 and represents approximately 16,000 members employed mainly in NHS and private laboratories, veterinary laboratories, the National Blood Authority, Health Protection Agency, Medical Research Council and Department for Environment, Food and Rural Affairs.

**The International Collaboration for Participatory Health Research** produce position papers which are an important forum for defining and debating the practice and principles of participatory research in health.

**The Market Research Society (MRS)** are available across a range of research practice areas and industry sections, covering topics such as questionnaire design, incentives and online research. The Society champions high ethical, commercial and methodological practices in research.

**Medical Research Council** All MRC-funded researchers must comply with MRC Ethics and Governance guidelines to ensure that their work is of a high scientific standard, is conducted safely, and respects the wishes and integrity of any patients or volunteers involved.

The MRC has also produced a number of useful online tool kits for particular types of research:

- **MRC Data and Tissues Tool Kit** (the use of personal information and human tissue samples in healthcare research in the UK)
- **Clinical Trials Tool Kit** (joint initiative with the Department of Health)
- **MRC Experimental Medicine Tool Kit**

The MRC Clinical Trials Unit has a very good explanatory section about clinical trials. This information is principally directed at members of the public who are thinking of participating in a trial but through the Glossary and FAQs page, it is also very useful for researchers too and can be found [here](#)

**The National Centre for the Replacement, Refinement and Reduction of Animals in Research** works in partnership with bioscience research funders, academia, industry, regulators and animal welfare organisations to advance the 3Rs [replacement, refinement and reduction] of animals in research.

**The National Research Ethics Service (NRES)** provides ethical guidance and management support to research ethics committees in England and delivers the quality assurance framework for the Research Ethics Service

**The Nuffield Council on Bioethics** examines ethical issues raised by new developments in biology and medicine. Established by the Nuffield Foundation in 1991, the Council is an independent body, funded jointly by the Foundation, the Medical Research Council and the Wellcome Trust.

**The Nutrition Society** was established in 1941 'to advance the scientific study of nutrition and its application to the maintenance of human and animal health'

**The Research Ethics Guidebook; a resource for social scientists** is designed as a resource for social science researchers - those early in their careers, as well as more experienced colleagues.

**The Royal Academy of Engineering** has developed, in collaboration with Engineering Council (UK) and a number of the leading professional engineering institutions, a statement of ethical principles which all professional engineers and related bodies should adhere to.

**The Royal College of Nursing (RCN)** represents nurses and nursing, promotes excellence in practice and shapes health policies

**The Royal Society for Chemistry** is the largest organisation in Europe for advancing the chemical sciences. Supported by a worldwide network of members and an international publishing business, our activities span education, conferences, science policy and the promotion of chemistry to the public. All RSC members are bound by its Code of Conduct and Guidance on Professional Practice

**The Social Research Association** maintains an up-to-date set of ethical guidelines and is proactive in the discussion of social research.

**The UK Research Integrity Office (UKRIO)** is an independent body which offers advice and guidance to universities and other research organisations, and also to individual researchers, about the conduct of research.

**US Department of Health and Human Services** Office for Human Research Protections: [International Compilation of Human Research Standards](#) – 2014 this document provides information on (country by country) the laws on data protection / codes of research ethics - a useful reference for applications to conduct research overseas.

**The Universal Ethical Code for Scientists** is a public statement of the values and responsibilities of scientists and applies to anyone whose work uses scientific methods, including social, natural, medical and veterinary sciences, engineering and mathematics."

**Wellcome Trust** has a series of accessible policy and position statements that outline their expectations of the research ethics applied by researchers which can be found [here](#). The statements cover a range of issues including: good research practice; research involving human participants and personal data; intellectual property and patenting; research involving people in low and middle income countries; and medical research.

## 20. Explanation of Terms

<b>Academic misconduct</b>	<p>Although not a comprehensive or precise definition, academic misconduct can be recognised to cover at least two broad categories. The first involves fabrication or falsification of research results; and the second arises where there is plagiarism, misquoting or misappropriation of the work of others. It also includes, for example, breach of trust (e.g. dishonesty towards research colleagues or subjects about the purpose, methods and intended/possible uses of research, and any risks involved); breach of impartiality towards research subjects; breach of confidentiality (re information supplied by research subjects and anonymity of respondents); the unethical use of material provided in a privileged way for review or assessment; deliberate or negligent deviations from accepted practices in carrying out research, which includes failure to follow established protocols. Colluding in, or concealing, the misconduct of others is, in itself, misconduct. Northumbria's Academic Misconduct in Research Policy is under the HR section <a href="#">here</a> This includes the procedure for investigating allegations of academic misconduct and applies to all staff employed at the University and also to individuals on honorary appointments and on secondment to the University. However, the employing organisation will be responsible for any formal disciplinary action that may result.</p>
<b>Adverse events</b>	<p>An untoward event or omission that could give rise to, or has the potential to produce, unexpected or unwanted effects which could be to the detriment of the safety of research participants, students or staff of Northumbria University.</p> <p>An incident includes, but is not limited to, breaches of security, violence, psychological distress. It includes near misses where an incident had the potential to cause injury, harm or disruption had intervention or evasive action not been taken. Some examples of possible adverse events that may occur within research include:</p> <ul style="list-style-type: none"> <li>• An incident involving violence or intimidation during a research interview.</li> <li>• Theft or damage to property during a research activity.</li> <li>• Accidental injury to a research participant or to a student or member of staff during a research activity.</li> </ul> <p>A 'no blame' policy is operated and it is therefore not University procedure to use reported incidents to attribute blame to any individual.</p>
<b>Animal subjects</b>	<p>Any vertebrate, other than human (mammals, birds, reptiles, fish, amphibian) and the invertebrate species.</p>
<b>Clinical trial</b>	<p>A clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials may also be referred to as intervention trials. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments, process-of-care changes, preventative care etc.</p> <p>For the purposes of insurance, a clinical trial is defined as "an investigation, or a series of investigations, conducted on any person for a medical purpose, where 'medical purpose' means</p> <ul style="list-style-type: none"> <li>• treating or preventing disease</li> <li>• diagnosing disease or ascertaining the existence, degree or extent of a physiological or psychological condition</li> </ul>



	<ul style="list-style-type: none"> <li>• assisting with or altering in any way the process of conception in methods of contraception</li> <li>• inducing anaesthesia</li> </ul> <p>otherwise preventing or interfering with the normal operation of a physiological condition"</p>
<b>Commercial loss</b>	It is necessary to ensure that there is adequate indemnity cover against Intellectual Property infringement by staff carrying out consultancy work via the University. Staff should be aware of limitations to professional indemnity cover. The University's public liability cover does not cover financial loss, but this can be arranged for specific projects.
<b>Covert research</b>	<p>Research that is conducted among groups where some participants are not aware they are taking part in a research study. Ethical codes of practice emphasise researchers should only collect data that is relevant and for which consent has been obtained. However, it is argued there are instances where covert research or research by deception might be justifiable, e.g.</p> <ul style="list-style-type: none"> <li>• informing participants of the research purpose will affect their behaviour and influence the results</li> <li>• the research is in the interests of the general public, and for the greater good, for example to expose how some organisations or institutions operate</li> <li>• it is not possible to obtain consent from all participants who will enter the arena being observed.</li> </ul> <p>Studies considering the use of covert research methods must be informed by a thorough consideration of their ethical implications by the Faculty Research Ethics Committee and be in line with the 1998 Data Protection Act.</p>
<b>The Data Protection Act (1998)</b>	The Act ensures that sensitive or personal data is held in confidence and protected from disclosure to a third party without the permission of the person about whom it is recorded. Anyone collecting or storing personal data has an obligation to practice 'fair processing' of the data. This means that when collecting personal data from individuals, they should always be made aware of the purpose for which it is being collected and how it shall be used.
<b>Data that comes under the Official Secrets Act</b>	Data that must comply with legislation that provides for the protection of state secrets and official information, mainly related to national security.
<b>Deception</b>	<p>Deception occurs where the participant is unable to give informed consent to take part in the research due to the deliberate presence of misleading information regarding the research and/or missing information regarding the research.</p> <p>Deception should be a last resort, and a clear case that it is required needs to be established. It also needs to be established that participants will not be unduly affected during the study by the deception, and will not be distressed at debrief when the deception is revealed.</p>
<b>Discomfort or safety concerns for participants</b>	Any task associated with the research study that could cause physical, social or psychological discomfort, inconvenience or danger, or could create any unacceptable level of risk, to participants.
<b>Environmental Issues</b>	Any outdoor fieldwork in rural, coastal, marine or urban environments and the temporary or long term effects the research study may have on people, animals or the natural or built environment.
<b>ESRC Research Ethics Framework</b>	This Research Ethics Framework (REF) is intended to sustain and encourage good ethical practice in UK social science research. It provides a frame of reference for research involving social science. This document sets out what the Economics and Social Research Council (ESRC) requires by way of ethics approval for the research it is asked to support, and sees as good practice for all social science research. Whilst the REF is available

	for use by other funders if they wish, it is mandatory for ESRC funded research.
<b>EudraCT</b>	This is a database of all clinical trials in the European Community that has been established in accordance with EU Directive 2001/20/EC. Through the website, you can obtain a EudraCT number, and complete, save and print an electronic version of the clinical trial application form which can be found <a href="#">here</a> .
<b>EU CTD</b> (European Union Clinical Trial Directive)	Overall, the Directive aims to provide an environment for conducting clinical research that protects participants without hampering the discovery of new essential medicines.  The main aim of the Directive is to simplify and harmonise the administrative provisions governing clinical trials by establishing a clear, transparent procedure and creating conditions conducive to the effective co-ordination of such clinical trials in the European Community by the authorities concerned.
<b>EU TCD</b> (European Union Tissues and Cells Directive)	The EUTCD creates a common framework that ensures high standards in the procurement, testing, processing, storage, distribution and import / export of tissues and cells across the EU community. It can be found <a href="#">here</a>
<b>GAfREC</b> (Governance Arrangements for NHS Research Ethics Committees)	The remit of a NHS research ethics committee in England is outlined in GAfREC. Northern Ireland and Wales endorse GAfREC as a standard for the governance of their research ethics committees.  RECs in Scotland are governed by a separate but similar version of GAfREC.  Visit the <a href="#">National Research Ethics Service</a> and search for GAfREC
<b>Health Research Authority (HRA)</b>	HRA Approval is now the route for all project-based research to commence in the NHS in England. Existing studies will be brought under HRA Approval arrangements. - See more <a href="#">here</a>
<b>Human Participants</b>	Human participants or subjects are defined as including living human beings, human beings who have recently died, (cadavers, human remains and body parts), embryos and foetuses, human tissue and bodily fluids, human data and records (such as but not restricted to medical, genetic, financial, personnel, criminal or administrative records including scholastic achievements).
<b>Human Tissue Authority (HTA)</b>	Since 1 September 2006, establishments storing tissue for research must be licensed by the Human Tissue Authority (HTA). The Human Tissue Act (2004) requires that consent must be given for body parts, organs and tissue from the living or deceased to be removed, stored or used for certain specified purposes.
<b>HTA licence</b>	An HTA licence ensures establishments meet the consent and other standards relating to the removal, storage and use of human tissue. If you are storing material which is not for an ethically approved project you must be satisfied that an HTA licence is in place (or move the tissue to licensed premises); without a licence, you will be acting illegally.  It is lawful to keep and use tissue samples without consent if they were held before 1 September 2006 – the date on which the requirement for consent came into force. If you have any concerns over whether your activity falls within the parameters of unlicensed activity please visit the <a href="#">HTA website</a>
<b>Human Tissue</b>	Any material that has come from a human body that consists of, or includes human cells, with the exception of hair and nails from living people, and living gametes and embryos created outside of the human body.

<b>Indemnity insurance</b>	<p>Non-NHS research undertaken by staff or students of Northumbria University is insured by the University. Clinical trials require separate insurance arranged on a case by case basis. Refer to the <a href="#">ethics and governance web page</a> and contact <a href="mailto:ethicssupport@northumbria.ac.uk">ethicssupport@northumbria.ac.uk</a> for further information.</p> <p>For NHS research, RECs require that you have an official written confirmation of indemnity cover. Please refer to chapter; Insurance Cover in Relation to Research</p>
<b>Informed consent</b>	<p>Informed consent is required when the research involves gathering personal data about individuals, or human participants. In English Law Children between the age of 16 and 18 years can consent for themselves (Family Law Reform Act 1969), unless they have a mental illness or learning disability. It is, however, the policy of the University to obtain permission from all participants under the age of 18 (plus under 16s) as well as the assent of their parents or guardians before any work takes place.</p> <p>Where parents/guardians are required to give their assent an explanatory statement should be produced. The consent form should accompany this statement and should only be signed and accepted if:</p> <ul style="list-style-type: none"> <li>• they have read and understood the explanatory statement, and</li> <li>• they agree that their child/children may participate in the research.</li> </ul> <p>The Mental Capacity Act 2005 provides a statutory framework in England and Wales to empower and protect vulnerable people who are not able to make their own decisions. Research involving, or in relation to, a person lacking capacity may be lawfully carried out if an “appropriate body” (a National Research Ethics Service research ethics committee) agrees that the research is safe, relates to the person’s condition and cannot be done as effectively using people who have mental capacity.</p>
<b>IRAS</b> (Integrated Research Application System)	<p>This is the Is a single system for applying for the permissions and approvals for health and social care/community care research in the UK. IRAS captures the information needed for the relevant approvals from the following review bodies:</p> <ul style="list-style-type: none"> <li>• Administration of Radioactive Substances Advisory Committee (ARSAC)</li> <li>• Gene Therapy Advisory Committee (GTAC)</li> <li>• Medicines and Healthcare products Regulatory Agency (MHRA)</li> <li>• Ministry of Justice</li> <li>• NHS/HSC R&amp;D offices</li> <li>• NRES/NHS/HSC research ethics committees</li> <li>• National Information Governance Board (NIGB)</li> <li>• National Offender Management Service (NOMS)</li> <li>• Social Care Research Ethics Committee</li> </ul>
<b>Medicinal products</b>	<p>Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological or psychological functions by exerting pharmacological, immunological or metabolic action or to make a medical diagnosis.</p>
<b>The Mental Capacity Act 2005</b>	<p>The Mental Capacity Act 2005 covers England and Wales and provides a statutory framework to empower and protect vulnerable people who are not able to make their own decisions. It makes it clear who can take decisions, in which situations, and how they should go about this. It enables people to plan ahead for a time when they may lose capacity. The full act can be found <a href="#">here</a>.</p>

	<p>[Note: separate legislation applies in Scotland (The Adults with Incapacity (Scotland) Act 2000) and separate legislation is expected in Northern Ireland.]</p> <p>Carers or nominated third parties must be consulted and agree that the person would want to join an approved research project. If the person shows any signs of resistance or indicates in any way that he or she does not wish to take part, the person must be withdrawn from the project immediately. Transitional regulations will cover research started before the Act where the person originally had capacity to consent, but later lost capacity before the end of the project</p> <p>The research provisions of the Act came into force in England and Wales on 1 October 2007.</p> <p>All research ethics committees established in England and Wales under the Act are appropriate bodies for the purposes of approving research under both section 30 of the Act and the Loss of Capacity Regulations made under section 34 of the Act. Click <a href="#">here</a> for information and guidance about the approvals process.</p> <p>Standard operating procedures for research involving those unable to consent for themselves are also available</p>
<b>MHRA</b> (Medicines and Healthcare Products Regulatory Agency)	See <a href="#">MHRA website</a>
<b>NIHR</b> (National Institute for Health)	National Institute for Health Research (NIHR) is funded through the Department of Health to improve the health and wealth of the nation through research. It is a large, multi-faceted and nationally distributed organisation. See NIHR website
<b>NRES</b> (National Research Ethics Service)	<p>The National Research Ethics Service is part of the National Patient Safety Agency and has a dual mission to protect the rights, safety, dignity and well-being of research participants and to facilitate and promote ethical research that is of potential benefit to participants, science and society.</p> <p>NRES provides robust ethics review service through a network of approximately 80 NHS research ethics committees (RECs) in England. There are two types of REC: recognised and authorised.</p> <ul style="list-style-type: none"> <li>• Recognised RECs are able to review proposals for clinical trials of investigational medicinal products (CTIMPs). They can also review non-CTIMP research.</li> <li>• Authorised RECs may review all research applications except for those relating to CTIMPs.</li> </ul> <p>If you are applying to a NHS REC for ethics approval, you must use the form in the Integrated Research Applications System (IRAS). Once your form is ready to submit, you should telephone <u>one</u> of the following to book your application into a relevant REC: your local REC; the Local Allocation System (LAS); or the Central Allocation System (CAS). You should submit your application to the selected REC within four working days of making the booking. The REC is required to give an ethical opinion within 60 calendar days of the receipt of a valid application.</p> <p><a href="#">NRES website</a>  <a href="#">IRAS website</a>  See also NHS Research and Development Approval (below)</p>

<b>NHS Research Governance</b>  <b>Framework for Health and Social Care</b>	A framework that defines the broad principles of good research governance, ensuring that health and social care research is conducted to high scientific and ethical standards. For further information click <a href="#">here</a> .
<b>NHS Research and Development Approval</b>	<p>[The text has been copied from NRES website <a href="#">here</a>.]</p> <p>“The Department of Health’s Research Governance Framework for Health and Social Care (RGF) requires NHS organisations to ensure that before any research involving human participants, their organs, tissue or data commences:</p> <ul style="list-style-type: none"> <li>• there are adequate arrangements and resources to meet the standards set out in the RGF;</li> <li>• an identified sponsor has taken on responsibility for the study;</li> <li>• the study has received ethics approval (where required);</li> <li>• there is a clinical trial authorisation in place for a clinical trial of a medicine;</li> <li>• the allocation of responsibilities is agreed and documented;</li> <li>• appropriate contractual arrangements are in place;</li> <li>• legislation relating to the research is followed within the organisation;</li> <li>• a person authorised to do so has given written permission on behalf of the NHS organisation.</li> </ul> <p>“The process of conducting the above checks and giving written permission is called NHS permission for research, often described as R&amp;D approval. In most NHS organisations an R&amp;D office or network is responsible for carrying out the relevant checks before permission is given by the chief executive or a delegated senior person.</p> <p>“All applications for R&amp;D approval from NHS organisations (or from health and social care organisations in Northern Ireland) are made using the Integrated Research Application System (IRAS). Applications should be made to each relevant NHS organisation.”</p>
<b>NHS staff, patients, premises or equipment</b>	Research conducted with staff currently employed on a full-time or part-time basis within the National Health Service (NHS); research being conducted on patients currently being treated in NHS facilities; research being conducted in any facility or establishment which is recognised as being part of the NHS.
<b>Personal data</b>	<p>In the context of the 1998 Data Protection Act, personal data is any information that affects a person’s privacy such as:</p> <ul style="list-style-type: none"> <li>• information which is biographical in a significant sense</li> <li>• has the relevant individual as its focus rather than some other person or some transaction or event.</li> </ul> <p>For further information <a href="#">click here</a></p>
<b>Principal Investigator (PI)</b>	The researcher recognised by the funding body as formally responsible, within the team of researchers, for the design, conduct and reporting of the study.
<b>Records management</b>	<p>“Appropriate technical and organisational measures shall be taken against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data”. (7th Data Protection Principle)</p> <p>If a research project requires the use of personal information, the researcher has a duty to uphold the rights of the individuals, as laid out in</p>

	<p>the Data Protection Act 1998. This means that the information should be stored in a secure manner so as to protect it from unauthorised access or theft. The key to the 7th principle is “appropriate technical and organisational measures”. This means that it is not necessary to implement over the top security systems, but at the same time, it does not give an excuse not to protect information.</p> <p>Even where a project does not involve personal data, maintaining the integrity of research records through secure storage should be a priority. See the University policy on data protection and secure storage of research records <a href="#">here</a>.</p>
<b>Research governance framework for health and social care:</b>	A framework that defines the broad principles of good research governance, ensuring that health and social care research is conducted to high scientific and ethical standards. Further information can be viewed <a href="#">here</a> .
<b>NHS Research Passport</b>	<p>A Research Passport is the mechanism for non-NHS staff to obtain an Honorary Research Contract or Letter of Access that will enable them to undertake research in the NHS.</p> <p>You should apply for a Research Passport if you have no contractual relationship with the NHS and you are proposing to carry out research in the NHS. If you are unsure whether you require a Research Passport please contact the Research and Development office at the Trust where you intend to carry out your research for clarification.</p> <p>You will not need a Research Passport or an honorary research contract if:</p> <ul style="list-style-type: none"> <li>• you are a student on a healthcare placement; or</li> <li>• you have an honorary clinical contract with the NHS (e.g. clinical academics); or</li> <li>• you are employed by an NHS organisation; or</li> <li>• you are an independent contractor (e.g. GP) or employed by an independent contractor</li> </ul> <p>An application form for a research passport and instructions about how to complete the form are available <a href="#">here</a>.</p>
<b>Safety concerns for researchers</b>	Any task associated with the research study that could cause physical, social or psychological discomfort, inconvenience or danger, or could create any unacceptable level of risk, to researchers.
<b>Sensitive subjects such as trauma</b>	Any subject that could cause psychological or social discomfort or distress to participants
<b>Sponsor</b>	<p>The sponsor takes primary responsibility for ensuring that the design of the study meets appropriate standards and that arrangements are in place to ensure appropriate conduct and reporting. The sponsor is usually, but does not have to be, the main funder. It can be the lead employer of the research team, or the lead health or social care organisation.</p> <p>The University will determine on a case-by-case basis whether or not it is prepared to sponsor a research project. It will normally expect only to sponsor research where its employees or students are the principal investigator or local research lead. Where necessary the University will share sponsorship arrangements with an appropriate body. The University expects that for commercial research the company that initiated the project will always act as sponsor.</p>
<b>Vulnerable people, including children</b>	<p>Persons under 18 years old or persons aged 18 years or older and any of the following:</p> <ul style="list-style-type: none"> <li>• living in residential accommodation, such as a care home or residential special school;</li> </ul>

	<ul style="list-style-type: none"> <li>• living in sheltered housing;</li> <li>• receiving domiciliary care in his or her own home;</li> <li>• receiving any form of health care that affects decision-making such that the ability to give informed consent is compromised;</li> <li>• detained in a prison, remand centre, young offender institution, secure training centre or attendance centre or under the powers of the Immigration and Asylum Act 1999;</li> <li>• in contact with probation services;</li> <li>• receiving a welfare service of a description to be prescribed in regulations;</li> <li>• receiving a service or participating in an activity which is specifically targeted at people with age-related needs, disabilities or prescribed physical or mental conditions. (Age related needs includes needs associated with frailty, illness, disability or mental capacity);</li> <li>• an expectant or nursing mother living in residential care;</li> <li>• receiving direct payments from local authority/HSS body in lieu of social care services;</li> <li>• requiring assistance in the conduct of his or her own affairs.</li> </ul>
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