20. Explanation of Terms

Academic misconduct	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 here 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.
Adverse events	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. 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: • 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. A 'no blame' policy is operated and it is therefore not University procedure to use reported incidents to attribute blame to any individual.
Animal subjects	Any vertebrate, other than human (mammals, birds, reptiles, fish, amphibian) and the invertebrate species.
Clinical trial	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. 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 • treating or preventing disease • diagnosing disease or ascertaining the existence, degree or extent of a physiological or psychological condition

	• assisting with or altering in any way the process of conception in methods of contraception • inducing anaesthesia otherwise preventing or interfering with the normal operation of a physiological condition"
Commercial loss	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.
Covert research	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. • informing participants of the research purpose will affect their behaviour and influence the results • 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 • it is not possible to obtain consent from all participants who will enter the arena being observed. 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.
The Data Protection Act (1998)	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.
Data that comes under the Official Secrets Act	Data that must comply with legislation that provides for the protection of state secrets and official information, mainly related to national security.
Deception	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. 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.
Discomfort or safety concerns for participants	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.
Environmental Issues	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.
ESRC Research Ethics Framework	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.
EudraCT	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 here.
EU CTD (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.
EU TCD (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 here
GAfREC (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 National Research Ethics Service and search for GAfREC
Health Research Authority (HRA)	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 here
Human Participants	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).
Human Tissue Authority (HTA)	Since1 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.
HTA licence	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 HTA website
Human Tissue	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.

Indemnity insurance	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 ethics and governance web page and contact ethicssupport@northumbria.ac.uk for further information. 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
Informed consent	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. 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: • they have read and understood the explanatory statement, and • they agree that their child/children may participate in the research. 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.
IRAS (Integrated Research Application System)	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: • Administration of Radioactive Substances Advisory Committee (ARSAC) • Gene Therapy Advisory Committee (GTAC) • Medicines and Healthcare products Regulatory Agency (MHRA) • Ministry of Justice • NHS/HSC R&D offices • NRES/NHS/HSC research ethics committees • National Information Governance Board (NIGB) • National Offender Management Service (NOMS) • Social Care Research Ethics Committee
Medicinal products	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.
The Mental Capacity Act 2005	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 here.

	[Note: separate legislation applies in Scotland (The Adults with Incapacity (Scotland) Act 2000) and separate legislation is expected in Northern Ireland.] 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 The research provisions of the Act came into force in England and Wales on 1 October 2007. 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 here for information and guidance about the approvals process. Standard operating procedures for research involving those unable to consent for themselves are also available
MHRA (Medicines and Healthcare Products Regulatory Agency)	See MHRA website
NIHR (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
NRES (National Research Ethics Service)	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. 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. • Recognised RECs are able to review proposals for clinical trials of investigational medicinal products (CTIMPs). They can also review non-CTIMP research. • Authorised RECs may review all research applications except for those relating to CTIMPs. 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 one 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. NRES website IRAS website See also NHS Research and Development Approval (below)

NHS Research Governance **Framework for Health and Social Care**	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 here.
NHS Research and Development Approval	[The text has been copied from NRES website here.] "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: • there are adequate arrangements and resources to meet the standards set out in the RGF; • an identified sponsor has taken on responsibility for the study; • the study has received ethics approval (where required); • there is a clinical trial authorisation in place for a clinical trial of a medicine; • the allocation of responsibilities is agreed and documented; • appropriate contractual arrangements are in place; • legislation relating to the research is followed within the organisation; • a person authorised to do so has given written permission on behalf of the NHS organisation. "The process of conducting the above checks and giving written permission is called NHS permission for research, often described as R&D approval. In most NHS organisations an R&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. "All applications for R&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."
NHS staff, patients, premises or equipment	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.
Personal data	In the context of the 1998 Data Protection Act, personal data is any information that affects a person's privacy such as: • information which is biographical in a significant sense • has the relevant individual as its focus rather than some other person or some transaction or event. For further information click here
Principal Investigator (PI)	The researcher recognised by the funding body as formally responsible, within the team of researchers, for the design, conduct and reporting of the study.
Records management	"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) 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

	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. 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 here.
Research governance framework for health and social care:	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 here.
NHS Research Passport	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. 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. You will not need a Research Passport or an honorary research contract if: • you are a student on a healthcare placement; or • you have an honorary clinical contract with the NHS (e.g. clinical academics); or • you are employed by an NHS organisation; or • you are an independent contractor (e.g. GP) or employed by an independent contractor An application form for a research passport and instructions about how to complete the form are available here.
Safety concerns for researchers	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.
Sensitive subjects such as trauma	Any subject that could cause psychological or social discomfort or distress to participants
Sponsor	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. 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.
Vulnerable people, including children	Persons under 18 years old or persons aged 18 years or older and any of the following: • living in residential accommodation, such as a care home or residential special school;

	• living in sheltered housing; • receiving domiciliary care in his or her own home; • receiving any form of health care that affects decision-making such that the ability to give informed consent is compromised; • 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; • in contact with probation services; • receiving a welfare service of a description to be prescribed in regulations; • 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); • an expectant or nursing mother living in residential care; • receiving direct payments from local authority/HSS body in lieu of social care services; • requiring assistance in the conduct of his or her own affairs.