

Glossary of terms for Ethics and Governance

Adverse events	<p>An incident is an untoward or adverse 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"> • 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. <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>
Animal subjects	<p>Ethical practice requires that the use of animals is justified and pain, suffering, distress, lasting harm, or the disturbance of wild animals avoided or at least kept at a minimum. Statutory controls and codes of practice must be observed at all times</p>
BERA	<p>British Educational Research Association to see its guidelines for educational research go to http://www.bera.ac.uk/guidelines.html</p>
CAS	<p>Central Allocation System, the booking system administered by the National Research Ethics Service for applications to be reviewed by recognised RECs. Bookings of applications relating to a CTIMP or a multi-site study in two or more domains is made through CAS. Multi-site studies in a single domain are normally submitted direct to local RECs but may be allocated through CAS</p>
Clinical Trial	<p>Any investigation in human participants, other than a non interventional trial, intended:</p> <ul style="list-style-type: none"> • to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more medicinal products • to identify any adverse reactions to one or more such products, or • to study absorption, distribution, metabolism and excretion of one or more such products with the object of ascertaining its (their) safety or efficacy of those products. <p>For the purposes of insurance a clinical trial is defined as:</p> <p>A clinical trial is an investigation or a series of investigations conducted on any person for a medicinal purpose, meaning:</p> <ul style="list-style-type: none"> • 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 from participating in methods of contraception • inducing anaesthesia • otherwise preventing or interfering with the normal operation of a physiological condition
Commercial Loss	<p>There is a need to ensure that there is adequate indemnity cover against IP infringement by staff carrying out consultancy work via the university.</p> <p>Staff should be aware of limitations to professional indemnity cover. The university public liability cover does not cover financial loss but this cover can be arranged for specific projects</p>
Consent Form	<p>This is the form signed by participants to confirm that they have had sufficient information to enable them to make an informed decision.</p> <p>It should have a brief introduction, restating the study title and aims and give clear instructions to the reader. 'Tick boxes' are usually easy to understand. Your statements should be written in</p>

	<p>the first person, for example:</p> <p>I have read and understand the purpose of the study <input type="checkbox"/></p> <p>I have had the chance to ask questions about the study and these have been answered to my satisfaction <input type="checkbox"/></p> <p>I am willing to be interviewed <input type="checkbox"/></p> <p>I am happy for my comments to be tape-recorded <input type="checkbox"/></p> <p>I understand that I can withdraw at any time if I change my mind and this will not affect my treatment/education/care <input type="checkbox"/></p> <p>I know that my name and details will be kept confidential and will not appear in any printed documents. <input type="checkbox"/></p> <p>NB: This is not a complete list or necessarily pertinent to all studies – it is for guidance only. The NHS NRES site gives useful examples. See http://www.nres.npsa.nhs.uk/ You should provide a space on the form for the participant's signature alongside your own and make sure the form has a version number and is dated. If your study involves participants with different levels of understanding, for example NHS staff and patients with learning difficulties, or teachers, pupils and parents, you must include separate consent sheets for each sample group. Where participants are unable to give consent, for example, young children, people with severe communication difficulties/learning difficulties etc, you must look at the process of assent and have an appropriate form for the person who is going to assent to that person's participation. You will also need to be aware of the Mental Capacity Act which addresses issues in relation to consent. If you are applying for NHS approval, there is a specific section of the NRES form that has to be completed in relation to capacity to consent. The University also requires assent of parents/guardians if participants are less than 18 years of age. However participants under 18 years of age still need to agree to participate and be informed about what this entails. If the procedure changes all participants must be informed in writing and new consent forms signed. All data collected must be anonymised, unless the participants have waived anonymity. Where the research involves a level of risk to participants beyond that encountered in everyday life, an independent witness should also be present to sign the consent form</p>
COREC	See NREC below
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 purpose for which it is being collected and how it shall be used.
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.
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 ESRC requires by way of ethical 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	EudraCT is a database of all interventional clinical trials of medicinal products in the community.

	<p>It has been established in accordance with Directive 2001/20/EC. The sponsor portal is available on the Internet and gives access to the application in order to:</p> <ul style="list-style-type: none"> • get a EudraCT number http://eudract.emea.eu.int • complete, save and print an electronic version of the clinical trial application form
EU CTD	<p>European Union Clinical Trial Directive</p> <p>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. This would facilitate the internal market in medicinal products while at the same time maintain appropriate levels of protection for public health. Overall, the Directive aims to provide an environment for conducting clinical research that protects participants without hampering the discovery of new essential medicines.</p>
GAfREC	<p>Governance Arrangements for NHS Research Ethics Committees. See http://www.nres.npsa.nhs.uk/</p>
Human Tissue Authority	<p>From 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.</p>
HTA Licence	<p>An HTA licence ensures establishments meet the consent and other standards relating to the removal, storage and use of human tissue.</p> <p>If you are storing material which is not for an ethically approved project you must be satisfied an HTA licence is in place (or move the tissue to licensed premises) as you will be acting illegally without a licence.</p> <p>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 see the HTA flow charts attached, or access the link to HTA Research FAQs http://www.hta.gov.uk/about_hta/faqs.cfm</p> <p>If you are planning a project that requires the use of human tissue you need to consider: consent, getting ethical approval and the safe disposal of human tissue. You have a duty to abide by the legislation and ensure that you have taken all necessary measures. Contact the research office x4908.</p>
Indemnity Insurance	<p>Non-NHS research undertaken by staff or students of Northumbria University is insured by the University.</p> <p>Clinical trials require separate insurance arranged on a case by case basis. Contact the research support office x4908</p> <p>For NHS research, RECs require that you have an official written confirmation of indemnity cover. For this, you should contact the at the University brokers via the research support office to arrange indemnity once the go-ahead has been given to the research by your school research ethics committee. HCES have their own arrangements in place</p>
Informed Consent	<p>Informed consent is required when the research involves gathering personal data about individuals, or human participants.</p> <p>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 intellectual 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</p>

	<p>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"> ▪ they have read and understood the explanatory statement, and ▪ they agree that their child/children may participate in the research <p>The Mental Capacity Act 2005 provides a statutory framework to empower and protect vulnerable people who are not able to make their own decisions. Sections 30-34 of the Mental Capacity Act makes detailed provision relating to research involving <u>adults aged 16 or over who are unable to consent for themselves</u>. Research involving, or in relation to, a person lacking capacity may be lawfully carried out if an “appropriate body” (a 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> <p>Applications from researchers may be made to an “appropriate body” from 1 July 2007 with a view to ensuring compliance with the Act from 1 October 2007. All RECs established under GARfEC in England and Wales are appropriate bodies for the purposes of approving research. All new applications which require approval under the MCA (from 1 July) must be made via the Central Allocation System (CAS)</p> <p><i>Tips:</i> The NHS NRES site gives useful examples. See http://www.nres.npsa.nhs.uk</p>
<p>Information Sheets for participants</p>	<p>An easy to follow guide to your study, which is normally written as a personal message addressed to the participant. For example, you might use the following sub-headings:</p> <p style="padding-left: 40px;"> What is the study about? Why I have been asked? What I am being asked to do What happens if I do not want to participate What would happen if I agree and then change you’re mind? How will the data be collected? (tape recorded/videoed etc) What is said will be anonymised What will happen to the data that is gathered? How will the research report be disseminated? Who do I contact if I want to ask more questions about the study? </p> <p><i>Tips:</i> The NRES website has good examples of information sheets (and consent forms) and is worth looking at even if you do not need REC approval http://www.nres.npsa.nhs.uk/applicants/index.htm. It is suggested that you use the first person to help the participants feel the form is for them. If you choose this method then do stick to it for the whole of the information sheet and consent form.</p> <p>If your study involves more than one group of participants and those participants have different levels of understanding or need to know about different aspects of the research, for example NHS staff and clients or teachers, pupils and parents, you must include separate information sheets for each sample group. Where your sample involves children or young people then you should include information for parents or guardians and age appropriate information for children. You will need to address the information needs of participants who may not be able to read/write/understand English/communicate (e.g. marginal/minority groups, disabled, prisoners) should they be involved in your research.</p>
<p>LREC Local Research Ethics Committee</p>	<p>LRECs are the local committees that scrutinise NHS related research. There are many of them around the country. For a list of LRECs see http://www.nres.npsa.nhs.uk/ The process of submitting your study is, however, identical for all LRECs. You need to fill in an electronic form, known and this is also found at http://www.nres.npsa.nhs.uk/</p> <p>The form is web-based and somewhat cumbersome to use. You need to go carefully and read</p>

	<p>all the instructions. The IT helpline is, as it says, very helpful if you have IT problems with the form.</p> <p>There are full instructions on the web http://www.nres.npsa.nhs.uk/ for filling in the whole form in terms of its content and there are also question specific guidelines that are very helpful. Some of the questions may seem a little strange. Remember this form is designed for all NHS related research from massive internationally multi-centred random controlled trials of drugs to a small, local study of perceptions. Some of the sections may well not be applicable to you, and you can say this but do not leave a section blank.</p> <p>Take particular care in filling in sections A9 and A10. There are the heart of your research and will be keenly scrutinised by the LREC.</p>
The Mental Capacity Act 2005	<p>The Mental Capacity Act 2005 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 at http://www.opsi.gov.uk/acts/acts2005/50009--b.htm#30</p> <p>Research involving, or in relation to, a person lacking capacity may be lawfully carried out if an “appropriate body” (a 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. The research must produce a benefit to the person that outweighs any risk or burden. Alternatively, if it is to derive new scientific knowledge it must be of minimal risk to the person and be carried out with minimal intrusion or interference with their rights.</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 MCA will come into force in England and Wales on 1 October 2007. Applications from researchers may be made to an “appropriate body” from 1 July 2007 with a view to ensuring compliance with the Act from 1 October 2007. All RECs established in England and Wales under 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. All new applications which require approval under the MCA (from 1 July) must be made via the Central Allocation System (CAS). Detailed guidance can be found at http://www.nres.npsa.nhs.uk/docs/guidance/AWI_Guidance.pdf</p> <p>See standard operating procedures for research involving those unable to consent for themselves http://www.nres.npsa.nhs.uk/docs/guidance/SOPs_Section12.pdf</p>
MHRA	The Medicines and Healthcare products Regulatory Agency. See: http://www.mhra.gov.uk
Personal data	<p>In the context of the 1998 Data Protection Act, personal data is any information that affects a person’s privacy such as:</p> <p>Information which is biographical in a significant sense Individuals as its focus rather than some other person or some transaction or event. See www.dataprotection.gov.uk</p>
NREC	National Research Ethics Service (formerly COREC) –is a governmental department sponsored by the Department of Health that has set out the structure of the LRECs* and MRECs* and published the Research Governance framework used by local NHS Trusts. See http://www.nres.npsa.nhs.uk/index.htm

NHS Research Governance Framework for Health and Social Care	<p>The Research Governance Framework for health and social care defines the broad principles of good research governance ensuring that health and social care research is conducted to high scientific and ethical standards</p> <p>http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108962</p>
Principal Investigator (PI)	<p>The researcher recognised by the funding body as formally responsible, within the team of researchers, for the design, conduct and reporting of the study.</p>
Scientific Misconduct	<p>Although not a comprehensive or precise definition, scientific 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</p> <p>The procedure for investigating allegations of Scientific Misconduct is para 2.2 within the staff management procedures – see link below.</p> <p>This procedure 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> <p>http://northumbria.ac.uk/static/worddocuments/StaffManagementProcedures.doc</p>
Sponsor	<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>
Records Management	<p><i>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)</i></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 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.</p> <p>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 to not 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 records @ http://northumbria.ac.uk/static/worddocuments/dp_and_storage_policy.doc</p>
Research Passport	<p>The Research Passport is the mechanism for non-NHS staff to obtain an Honorary Research Contract (HRC) when the research they propose to carry out is likely to impact on NHS patient care.</p> <p>It is the document provided by NHS R&D offices to be completed by researchers and their Higher Education Institution (HEI) employer. Its purpose is to:</p>

	<ul style="list-style-type: none"> • List the pre-engagement checks the HEI employer has carried out; • Provide assurances from the HEI employer about the researcher; • Access multiple NHS organisations removing the need for duplicate checks; • Streamline the application process by minimising duplication, reducing delay and removing inconsistencies <p><u>Who needs a Research Passport?</u></p> <ul style="list-style-type: none"> • It is for researchers who have no contractual arrangements with the NHS but who conduct research in the NHS which can impact on patient care e.g. researchers with HEI employment contracts. <p><u>Who does not need a Research Passport?</u></p> <ul style="list-style-type: none"> • Researchers with NHS employment contracts The NHS has existing mechanisms for such staff to work across NHS organisations • Researchers with honorary clinical contracts (e.g. clinical academics) These researchers have joint NHS/ HEI posts which enable them to conduct clinical duties including research, and to work across NHS organisations through existing NHS systems <p>www.ukcrc.org/researchpassport.aspx</p>
<p>Trust Research and Development Committee</p>	<p>NHS Trust based research requires Research and Development Approval. All Trusts have a Research and Development Manager who you can ring for advice. The Trust will need to look at your research to ensure that the issues that may affect them in terms of resources eg how much time might you be asking busy staff to give up for your research are acceptable, proportionate and well thought through. There are very rare cases where research proposals can be turned down due to circumstances within the Trust. These might include, for example, staff or patients being over-researched which can happen when work is being done in a specialist area. <u>It is always better to have had discussions about your research before you start the proposal to check out that it will be acceptable.</u></p> <p>The current requirements are that you will need to send the following documents to the Trust, submitted to the R&D Manager:</p> <ul style="list-style-type: none"> • Electronic copies of REC Forms A, B and C. [C is the Site Specific Information (SSI) that Trusts need, make sure you send this as well as A and B.] • Printed copy of your SSI Form with signature(s) • Copies of all documents provided for the ethics review • Copy of honorary contract with the NHS organisation, where applicable • Written evidence from the organisation(s) acting as sponsor that they have agreed to accept the responsibilities of sponsor <p>If you are not an employee of the Trust it is likely that you will need an Honorary Contract. The Trust will send you the form to fill in. Depending on the content of your research study, you may also need a current CRB check. Remember, this will all take time. If you think this may apply to you do start earlier and make contact with the R&D office so that they can help you with this.</p>
<p>Vulnerable Participants</p>	<p>Children (< 18) Elderly participants. Learning disabled participants. Patient groups. Any participants who are unable to give informed consent.</p>