



TEESSIDE UNIVERSITY RESEARCH GOVERNANCE

POLICY, PROCEDURES

AND GUIDELINES

FOR

RESEARCH ETHICS

2017-18

Updated May-2018

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*Guidelines based on training materials designed by Dr Andrew C. Rawnsley.
Legal advice provided by Gary Singh, David Bridge and Kate Heljula.*

TEESSIDE UNIVERSITY RESEARCH GOVERNANCE

Principles, Procedures, and Guidelines for Research Ethics – 2018 Revision

Definition of Research

'Research' for the purposes of this document is to be understood as:

- original investigation undertaken in order to gain knowledge and understanding
- work of direct relevance to the needs of commerce, industry, and to the public and voluntary sectors
- scholarship
- the invention and generation of ideas, images, performances, artefacts including design, where these lead to new or substantially improved insights
- the use of existing knowledge in experimental development to produce new or substantially improved materials, devices, products and processes, including design and construction.

Definition of 'research activity'

Research activity is defined as *Teesside University research activity* where:

- TU takes on ultimate responsibility for the research, and/or, the activity is being undertaken in fulfilment (or part-fulfilment) of a TU programme of study/academic award,

and/or,

- A member of TU staff, or a student enrolled in TU is:
 - the Chief Investigator (CI) or Academic Supervisor,

and/or,

- holds the research funding

TEESSIDE UNIVERSITY RESEARCH ETHICS PRINCIPLES

Principle 1

Harm to research participants must be avoided: the protection of the dignity, rights, safety and well being of all actual and potential participants, researchers, non-participating members of the public, and the environment takes precedence over scientific, or any other, considerations or interests.

Principle 2

Research should be designed, reviewed and undertaken to ensure adherence to the highest standards of quality, integrity, ethical propriety and governance, and legal compliance.

Principle 3

Researchers and participants must normally be informed as fully as possible about the purposes, methods and intended possible uses of the research, what their participation in the research entails, and what risks and benefits are involved. This information should be accurate, clear, and easily understood by the potential participant, who should have the capacity to understand what is involved in their participation. Research proposing variation from this principle may be approved but only in very specific contexts in which the lack of proper information must be justified by the value of the research.

Principle 4

Research participants must consent to participate in a voluntary way, free from any coercion, undue influence, or manipulation. Use of inducements to encourage participation must be carefully monitored.

Principle 5

The confidentiality of information supplied by research participants, and their anonymity, must be respected except in cases where illegal behaviour is discovered. All data and other materials from and about research participants will be collected, processed, retained, stored, and disposed of, in accordance with current legal requirements.

Principle 6

The independence of research must be clear, and any conflicts of interest or partiality must be disclosed. Publication of research results must be done fairly and with the public good taking priority over private

PRINCIPLES ON THE USE OF PERSONAL IDENTIFIABLE DATA IN RESEARCH

The University, as a public institution, uses personally-identifiable information obtained from research participants to conduct research. As a publicly-funded organisation, the University has to ensure that it is in the public interest when personally-identifiable information from people who have agreed to take part in research is used. This means that when participants are recruited and agree to take part in a research study, the University will use such data in the ways needed to conduct and analyse the research study. Participant's rights to access, change or move personal information are limited, as there is a need to manage that information in specific ways in order for the research to be reliable and accurate. To safeguard participants' rights, the University will use the minimum personally-identifiable information possible.

The following data processing principles apply:

- a) Where possible, research projects will work with *fully anonymised data*;
- b) When anonymised data has been obtained initially as identifiable personal data, research projects will anonymise data as quickly as possible to render the data anonymised;
- c) If working with fully anonymised data is not possible or would render the purposes of the research invalid, then research projects will work with *pseudonymised data* that has been anonymised whilst retaining a key permitting re-identification within strictly controlled conditions and by strictly defined persons involved with the research. The key permitting re-identification must be kept separately from the data and any other documents relating to the person from whom the data was obtained;
- d) If working with pseudonymised data is not possible or would render the purposes of the research invalid, then research projects will work with the *minimal amount of personal data* as is strictly necessary in order that the research purpose will be achievable;
- e) Individuals from whom personal data is obtained will be informed that the basis upon which their personal data is being processed is for research and that the legal basis for processing their personal data for research is as a task carried out in the public interest;
- f) Where personal data is collected from individuals, they will also be informed about the uses to which their personal data will be put within a research project and their rights with respect to their personal data; whether, how and when their personal data will be anonymised or pseudonymised; and the right to withdraw personal data will be specified; and the time period in which withdrawal is possible will be made clear to them;
- g) When specifying data withdrawal rights to individuals from whom personal data is obtained for research purposes, it will be made clear to them that they are providing consent to participate in the research and consent for their data to be used for the purpose of research but that the legal basis on which their personal data will be processed is that of a task carried out in the public interest.

1.0 PROCEDURES

1.1 Ethical 'Clearance'

Ethical Clearance is required for *all* Teesside University (TU) research activity except those projects which consist *entirely* of literature review, desk or library-based research.

Projects which are entirely literature or desk and/or library-based do not need to receive ethical Clearance but staff and students undertaking such research should be familiar with the University's policies on use of the internet in research [Section 4 of this document]. Students, in particular, should also be made aware that some areas of literature and library-based research may nevertheless involve sensitive or controversial material which will require a degree of care when accessing and handling. Literature or library-based work which is *primarily* carried out *external* to the University, for instance in an off-site archive, requires ethical Clearance.

Ethical Clearance is obtained by application to the relevant School Research Ethics Committee (SREC) before research commences:

Members of Research Institutes should apply for ethical clearance via the SREC of the School to which the member is also affiliated. Staff should apply to the SREC of the School which employs them. Students should apply to the SREC of the School which awards the qualification, or academic credits for which they are studying.

Application can be made *via one of two routes*, using one of two forms:

a) application for ethical Release, using a Release Form [ETHREL];

or

b) application for ethical Approval using a Request for Ethical Approval Form [ETHAPP].

Which of these two routes (and which form) is appropriate depends upon the nature of the research and the risks and implications of the research project. It is vital that staff and students use the appropriate route, and application form, for their work or clearance may be delayed or invalid.

Each School has an individualized version of ETHREL and ETHAPP. Applications made to the relevant School must be on the correct School form.

For Ethical Release procedures see section headed 1.2

For Ethical Approval procedures see section headed 1.3

Certain elements of the section headed 1.4 will apply to applications for *both* Release *and* Approval and should be considered in addition to the specific procedures for the route.

For all levels of research, the Chair of the School REC has the option to *sign-off* clearance for Release form applications but, at their discretion, *they may refer any Release application to be resubmitted through the Approval route.*

1.2 ETHICAL RELEASE ROUTE

Ethical Release is designed to be a streamlined process for projects with **low ethical risk**. Different processes are involved for different levels of research which are described below. Ethical Release forms should be completed so as to demonstrate awareness of potential ethical issues and how the researcher will ensure conformity with Teesside's Principles, even if there are no obvious ethical issues. If there are no ethical issues, then ***it must be stated why there are no ethical issues***.

1.2.1 Staff research not being undertaken as part of a degree

Staff have the option to *self-certify* the ethical propriety of their research. If they wish to do this they may apply for ethical clearance through the Release route. In order for self-certification to be valid, staff must confirm as part of their application **that**:

- the work proposed conforms to the ethical standards established by the University's Research Ethics Sub-Committee and set out in the six **TU Principles for Research Ethics**, and
- they have sufficient understanding of the ethical implications of their work and that they have undertaken the required training in research ethics and specifically, any
- research governance and ethics training required by their School.

Staff are required to certify this on a Research Ethics Release Form [*ETHREL*], and tick the *Type of Researcher* "Staff - Other Research" box. In all cases Ethical Release forms must include sufficient detail to demonstrate the applicant's awareness of potential ethical issues and how the researcher will ensure conformity with TU's Principles. Staff are advised to consider that by self-certifying their work they are indicating their agreement to accept full responsibility for the ethical propriety of that work. Staff who work in areas in which ethical issues tend to be more prominent and sensitive (such as Health and Social Care, Public Health, Social Work or research undertaken with particular populations such as vulnerable adults or children) will need to be very careful in undertaking such self-certification, and are advised to seek Clearance through ethical Approval rather than through Release routes. Schools may also have their own specific policies regarding ethical clearance, which in some cases may require *all* research to be cleared via ethical Approval. The potential risk in not seeking clearance via Approval is that, in self-certifying, staff may well be putting themselves, the research participants, and/or their work and their own and TU's reputations at risk. Staff are also advised to note that *where the approval of external regulatory bodies or agencies is required it is expected that they will normally use the **Approval route***.

1.2.2 **Postgraduate research students** **(PhD, MPhil, DProf, MProf, PhDCW, MPhCW)**

It is expected that in most cases postgraduate research students (including members of staff working towards a research degree award) will deal with the ethical clearance for their degree projects themselves in consultation with their academic supervisors. However, supervisors can also certify the propriety of their students' work. In those cases it is vital that both the member of staff and the research student have considered how their proposed work accords with the Teesside University Ethical Principles and can verify the statements which staff certify by signing the form. Staff are advised to consider that by certifying their students' work they are indicating their agreement to accept full responsibility for the ethical propriety of that work. Staff who work in areas in which ethical issues tend to be more prominent and sensitive (such as Health and Social Care, Public Health, Social Work or research undertaken with particular populations such as vulnerable adults or children) will need to be very careful in undertaking such certification, and are advised to have their students seek clearance through ethical Approval rather than through Release routes. Schools may also have their own specific policies regarding ethical clearance, which in some cases may require *all* research to be cleared via ethical Approval.

In all cases the application form must be signed by the Director of Studies (or pp'ed on their behalf by another member of the Supervisory Team in their absence). All communication about the application from the SREC concerned (including the decision letter) will be sent to the Director of Studies.

On the form the applicant must tick the "Postgraduate research student" or "Staff Higher Degree" *Type of Researcher* category box.

A copy of the Research Ethics Release form, approved by the SREC Chair, must be attached to the Progression form [UTRD PROG] submitted to the University Research Degrees Committee towards the end of the first year of study. The demonstration of adequate awareness of ethical issues in research projects will be a factor in approval for Progression on research degrees. The Chair of the SREC has the option to *sign-off* the Release form but, at their discretion, they may refer any release application to be resubmitted through the Approval route.

Risk Assessment procedures must be followed and the completed documentation included with all applications for projects which involve student researchers in the use of machinery, animals, chemicals, bio-active reagents, and others with potential personal risk to the researchers.

1.2.3 **Postgraduate professional ('taught') doctorate projects (DClynPsy, DBA, EdD, DHealthPsy, DCounPsy, PsyD, DHSC)**

It is expected that in most cases professional doctorate students will deal with the ethical clearance for their projects themselves in consultation with their academic supervisors. However, supervisors can also certify the propriety of their students' work. In those cases it is vital that both the member of staff and the student have considered how their proposed work accords with the Teesside University Ethical Principles and can verify the statements which staff certify by signing the form. Staff are advised to consider that by certifying their students' work they are indicating their agreement to accept full responsibility for the ethical propriety of that work. Staff who work in areas in which ethical issues tend to be more prominent and sensitive (such as Health and Social Care, Public Health, Social Work or research undertaken with particular populations such as vulnerable adults or children) will need to be very careful in undertaking such certification, and are advised to have their students seek clearance through ethical Approval rather than through Release routes. Schools may also have their own specific policies regarding ethical clearance, which in some cases may require *all* research to be cleared via ethical Approval.

In all cases the application form must be signed by the supervisor. All communication about the application from the SREC concerned (including the decision letter) will be sent to the student's academic supervisor(s).

On the form the applicant must tick the "Taught postgraduate student" *Type of Researcher* category box.

Risk Assessment procedures must be followed and the completed documentation included with all applications for projects which involve student researchers in the use of machinery, animals, chemicals, bio-active reagents, and others with potential personal risk to the researchers.

1.2.4 Taught Masters dissertations/projects

It is expected that in most cases taught masters students will deal with the ethical clearance for their projects themselves in consultation with their academic supervisors. In some cases supervisors may choose to certify the propriety of their taught master's students' work. In those cases it is vital that both the member of staff and the student have considered how their proposed work accords with the Teesside University Ethical Principles and can verify the statements which staff certify by signing the form. Staff are advised to consider that by certifying their students' work they are indicating their agreement to accept full responsibility for the ethical propriety of that work. Staff who work in areas in which ethical issues tend to be more prominent and sensitive (such as Health and Social Care, Public Health, Social Work or research undertaken with particular populations such as vulnerable adults or children) will need to be very careful in undertaking such certification, and are advised to have their students seek clearance through ethical Approval rather than through Release routes. Schools may also have their own specific policies regarding ethical clearance, which in some cases may require *all* research to be cleared via ethical Approval.

In all cases the application form must be signed by the supervisor. All communication about the application from the SREC concerned (including the decision letter) will be sent to the supervisor.

On the form the applicant must tick the "Taught postgraduate student" *Type of Researcher* category box.

Risk Assessment procedures must be followed and the completed documentation included with all applications for projects which involve student researchers in the use of machinery, animals, chemicals, bio-active reagents, and others with potential personal risk to the researchers.

1.2.5 Final Year undergraduate dissertations and projects

There are two distinct categories of undergraduate projects:

1) Those NOT involving human or animal participants and NOT involving potential physical or psychological risk to the researcher(s) themselves. These projects will usually be **entirely desk and/or library-based** and the same kind of research will be done by an entire group of students. These projects **DO NOT** require ethical Clearance. However, the member of staff responsible for the module in which such work is occurring **must keep a record that confirms that these projects meet the criteria** of “entirely desk and/or library-based” and such a record must be available for audit by UREC if requested.

2) Those which DO involve human or animal participants, and/or involving potential or psychological risk to the researcher(s) themselves. In these cases, ethical Clearance **WILL** be required. Release can be used for **individual** student projects with low risk. For higher risk projects, Approval should be used.

Procedure for projects requiring ethical Clearance

In some cases supervisors may choose to certify the propriety of their *undergraduate* students' work. In those cases it is vital that both the member of staff and the student have considered how their proposed work accords with the Teesside University Ethical Principles and can verify the statements which staff certify by signing the form. Staff are advised to consider that by certifying their students' work they are indicating their agreement to accept full responsibility for the ethical propriety of that work. Staff who work in areas in which ethical issues tend to be more prominent and sensitive will need to be very careful in undertaking such certification, and are advised to have students seek clearance through ethical Approval rather than through Release routes. Schools may also have their own specific policies regarding ethical clearance, which in some cases may require *all* research to be cleared via ethical Approval. In all cases the application form must be signed by the supervisor. All communication about the application from the SREC concerned (including the decision letter) will be sent to the supervisor. On the form the applicant must tick the —Final Year UG Student *Type of Researcher* category box.

1.2.6 Chair's Action or Full SREC Referral

The Chair of the SREC must complete and sign the Research Ethics Approval section of the relevant form for all projects. The Chair may decide that they cannot approve a project submitted on a Release or Block Release Form, in which case it would be referred to the SREC. The Research Ethics Approval Section of the appropriate form is then completed when the SREC has considered and approved the research (as in the case of projects submitted using a Request for Ethical Approval form).

1.2.6.1 Cases of doubt

If a member of staff, a supervisor, or student, has concerns about the ethical propriety of a piece of research they should approach the Chair of the relevant SREC and/or the Research Governance and Training Manager (Graduate Research School) for advice as early in the project planning stage as is possible, and certainly well before preparing and submitting an application for Clearance.

1.3 ETHICAL APPROVAL ROUTE

For research *at any level* which involves potentially difficult ethical issues, particularly research with human participants or animals, or for which there is doubt over the conformity to the Teesside Principles, **an application for ethical Approval** must be made.

Such applications may be made using either the ***Request for Ethical Approval form [ETHAPP]*** or, if an application must also be made for approval via an external body (to avoid applicants having to complete two forms) the appropriate form generated via the Integrated Research Application System (IRAS).

All applications for clearance by Approval are submitted to and considered by the relevant SREC. Schools may also have their own specific policies regarding ethical clearance, which in some cases may require *all* research to be cleared via ethical Approval.

1.3.1 Supplementary documentation

If the research involves data collection from or about human participants, normally the following documentation will be attached to the application for clearance by the Approval route:

Participant Information Sheet

Explicit statement on legal basis for processing of personal identifiable data

Consent Form for participation in research

Data collection tools e.g. Questionnaires, Topic Guides for Focus Groups, Semi-structured interview questions (as appropriate)

As stated in TU principles one, three and four the expectation is that research with human participants will be conducted on the basis of **valid informed consent**.

Projects seeking clearance for methods involving variation from this may be approved by the relevant SREC but only in very specific contexts in which the lack of proper information is justified by the value of the research proposed and the University is not exposed to undue risk nor would insurance cover be compromised. The Chair of the relevant SREC may need to seek confirmation regarding TU's insurance status as part of the review process in such projects.

1.3.2 Contact Details

The personal contact details of researchers should not be used in study documentation - in all cases only University contact details should be used.

For non-doctoral student research the Academic Supervisor's University contact details should be used, or students should apply to their school for a special, anonymous, e-mail address for responses. For doctoral students, where there is no apparent risk to the student incurred by doing so, and the student and supervisor wish to, the student's University contact details may be used to allow potential participants to ask questions about the study and/or arrange participation (booking appointments etc).

If telephone contact details are required this should either be the supervisors TU number, the student's business number, or a dedicated number for that study only.

In all cases where recruitment is planned to include participants from out with the University population, and/or where the relevant SREC considers it necessary, the contact details of a member of TU staff (normally the Chair of the relevant SREC) must be provided (instead of, or in addition to, the student's) as the person to whom any complaints or concerns should be directed.

1.3.3 Research requiring approval by the National Research Ethics Service ¹

No University ethics committee can give **final** ethical approval to research that comes within the remit of the National Research Ethics Service (NRES). The NRES remit is described in the Governance arrangements for NHS Research Ethics Committees (Section 3) which is available at

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4005727

Applicants are advised to note that in all research where the Mental Capacity Act (2005) and/or the Human Tissue Act (2004) are relevant fall within the remit of NRES.

NRES also only consider applications for activities which they classify as Research and not Audits or Service Evaluation (see <http://www.nres.npsa.nhs.uk/rec-community/guidance/>). Applicants are advised to note that TU do not make such distinctions in research activity and the definition of these terms by NRES does not always coincide with definitions that may be used elsewhere.

¹ See NRES website at: <http://www.nres.npsa.nhs.uk>

If NRES classify any TU project as Research the project needs a minimum of three separate approvals:

Firstly TU approval (obtained via application for clearance by Approval to the relevant SREC) and then approval from an NRES REC and any other applicable body (such as the R&D Depts. of the Trust or Trusts, any Social Care or Social Work Research Approval Group or Committee).

If NRES classify any TU project as either an Audit or a Service Evaluation the project needs a minimum of two separate approvals:

Firstly TU approval (obtained via application for clearance by Approval to the relevant SREC) and then approval by any other applicable body (such as the R&D Depts. of the Trust or Trusts, any Social Care or Social Work Research Approval Group or Committee).

In all cases research that requires the approval of NRES may only be submitted to NRES after TU Clearance has been confirmed.

Researchers who do not have a prior contractual relationship with the NHS whose work involves NHS patients, staff, or premises, may also be required to obtain a Research Passport or letter of permission to conduct their research. Guidance on whether or not a Research Passport or other permissions are required is available at:

http://www.nihr.ac.uk/systems/Pages/systems_research_passports.aspx

This process is likely to require DBS (criminal record and/or safeguarding check), occupational health check, and/or identity verification.

1.3.4 Other issues relating to external (non-TU) approvals and permissions

It is the responsibility of the applicant for Clearance to determine which external approvals and permissions are required for the project they propose and to detail that in their application. It is the responsibility of the applicant to ensure that the Governance standards and requirements of all relevant external bodies or agencies are adhered to in the planning and conduct of the research. Criminal Record Bureau (CRB) checks are commonly needed for researchers working in certain areas.

SRECs will not accept an applicant's self-verification of such checks. As a result, documentary proof in some form must be included with any applications for Clearance.

1.3.6 Research Degree Registrations

In the case of students registering for a higher degree by research, in order that Chairs of School RECs can certify that the issues relating to ethical consideration have been addressed, and that the Principal Researcher/Supervisor has the appropriate expertise of the research area, a copy of Forms UTRD APP and UTRD REGSUP must be submitted to the Chair along with any application for ethical Approval.

A copy of the Research Ethics Approval form, signed by the SREC Chair, must be attached to the Progression form [UTRD PROG] submitted to the University Research Degrees Committee towards the end of the first year of study. The demonstration of adequate awareness of ethical issues in research projects will be a factor in approval for Progression on research degrees

Ethical clearance must have been obtained prior to the final approval of Progression by the Postgraduate Research Assessment Board.

1.4 OTHER PROCEDURAL ISSUES RELATING TO ETHICAL CLEARANCE

1.4.1 Inter School and Institutional collaboration

In cases where students or staff require access to facilities, staff or students in another school in order to undertake their research, project supervisors should write to the Associate Dean (Research & Innovation) of the appropriate school(s) to obtain written approval for access, before seeking ethical clearance from their own SREC. Researchers should be aware of potential for time delays and via project supervisors seek permission at an early stage.

Research involving collaboration between TU and other universities may necessitate obtaining ethical approval from both institutions. This will apply if primary research is being conducted using facilities at both institutions. As a rule, if any research activity is being conducted on Teesside University premises, even after primary work has taken place at another institution, then ethical clearance, normally via the release route, will also need to be obtained.

1.4.2 Cases of SREC concern

Where the SREC has concerns about the ethical propriety of research referred to it, these concerns will be sent in writing to the applicant and a response invited. In addition, a member of the SREC may be nominated to work with the researcher(s), to assist them in addressing the issues identified during review.

1.4.3 Referral to University REIC

When a School Research Ethics Committee [SREC] is unable, after dialogue with the researcher(s) concerned, to resolve concerns and assure itself of the ethical propriety of research, it shall refer the matter to the Dean of School for information and the Research Ethics & Integrity Committee for action. (UREIC)

Projects that fall under the remit of paragraph 1.4.10 Security-sensitive research will always be referred by the SREC to UREIC. Determination of which applications fall under the remit of paragraph 1.4.10 will be made using criteria provided to the Chairs of the SREC or, in cases in which there is any doubt, the Chair of SREC must refer to UREIC to determine applicability.

1.4.4 Appealing SREC decisions

Applicants may appeal a final decision made by an SREC, but only after first attempting to resolve any issue by dialogue with the SREC concerned. Appeals may be made only with regards to *procedural error* by an SREC and not on the basis of *ethical judgement and/or disagreement*. Appeals will be made to UREC, whose decision on appeal matters is final. Any appeal will be overseen by the Chair and Secretary of UREC.

1.4.5 Recruitment of participants for research projects

Recruitment of human participants must be done carefully and with respect, normally ensuring proper and valid consent is obtained from participants. Consent is obtained for participation in the research. Personal identifiable data obtained for the purposes of research will be processed on the basis of the University's task in the public interest.

If inducements of any kind are used, not exclusively but particularly monetary incentives (beyond expenses) to encourage participation, this must be done with careful consideration of the risk of manipulation and or coercion.

It is expected that members of staff will not normally be approached to be recruited as participants in student dissertations or research work.

Students who use the Teesside University logo for materials designed to recruit participants for research projects must use a specially amended 'research governance' version of the logo. Students should request the use of this logo via their supervisors who should contact the Governance staff in Research and Innovation Services. Staff are free to use the TU logo on their recruitment materials as is.

1.4.6 Research Ethics Training

In accordance with School policy, members of staff involved in Research may be required to attend Research Ethics Training, which is offered regularly throughout the academic year. Where staff who wish to self-certify their own work and/or certify the work of their students are unfamiliar with the concepts set-out in the Teesside Principles (conformity with which is attested to in certifying via ethical Release), they are strongly encouraged to attend training.

1.4.7 Use of the Internet in Research

In any project using the internet as a search or research tool the applicant must ensure that the researchers concerned are aware of, and have discussed, the 'Good Conduct in the Use of the Internet for Research' section of this document which follows at Section 4

1.4.8 External researchers access; School staff and/or students, premises, Equipment and/or expertise

TU encourages and assists external researchers wherever possible. Any external researcher who wishes to conduct research –

- employing TU staff and/or enrolled students as participants
and/or

- using TU premises, equipment or expertise in any way,

must seek and receive formal approval for that from - the relevant Subject Lead - for single Subject group domain research - or from the Associate Dean (Research and Innovation) in the appropriate School - for multiple or cross Subject domain research, prior to commencement of the research.

To enable accurate record keeping the person granting approval should notify the Chair of the relevant SREC and Governance staff in Research and Innovation Services in writing, both when approval is granted, and when the project is completed.

In all cases, prior to giving a decision to any external researcher, the AD for research and/or the relevant Subject Lead(s) must consider how the proposed research activity may impact upon students, student activities, course management and any Academic, Technical and/or Support staff that may be involved/affected.

1.4.9 Use of Freedom of Information or other legislation to obtain data

Researchers may not compel individuals or organisations to supply research data through the use of legislative provisions, for example by using the Freedom of Information Act or the Environmental Information Regulations. Applications for specific exceptions to this requirement can be submitted to the University's Research Ethics Committee for consideration on a case-by-case basis

1.4.10 Security-sensitive research

Research activities which involve topics, materials, or accessing of information and/or networks which may have serious security-sensitivity, or where the development of artefacts or applications as part of the research may be regulated for export or use outside the UK, must be referred by School Research Ethics Committees [SRECs] directly to the University Research Ethics & Integrity Committee (UREIC). Such projects may be purely text or internet-mediated and not necessarily involve human participants.

In considering referred projects, UREIC will obtain legal advice and the University may refuse to sponsor any research for which the legal basis is unclear. UREIC will maintain a record of all referrals, decisions taken about their status, and where particular arrangements must be made for the conduct of such projects. UREIC will define and record the terms of conduct which must be adhered to by the researcher(s) concerned.

It is the responsibility of individual researchers to make an application to the relevant SREC when proposing to conduct research of this kind so that the SREC can record the application and refer the project to UREIC. Failure to use the application process for projects which subsequently are found to lack a sound legal basis and for which a proper referral to UREIC is required will result

in any liabilities for the project resting with the researcher(s) and not with the University.

1.4.11 Use of regulated non-human genetic resources

Any research conducted using non-human genetic resources obtained after 12 October 2014 must comply with the legal requirements relating to the international Nagoya Protocol. These compliance duties require the obtaining of prior informed consent, the negotiation of mutually agreed terms and the conducting and maintenance of records of due diligence. Applicable non-human genetic resources are plant, animal, microbial, biomass, or food waste obtained from a nation that is party to the Nagoya Protocol.

2 Monitoring of Projects and Governance

2.1 Supervisors must monitor research projects to oversee continued ethical propriety. Research must be monitored in accordance with the University's "*Framework and Code of Practice for Ensuring Research Integrity*"² and other codes of practice relevant to the field.³

2.2 Filing of Release/Approval Forms.

A single copy of the Research Ethics Release or Approval form must be filed in the School administrative office upon completion and signature by the Chair of the SREC (or following approval upon referral to the University REC).

As part of post-clearance audit procedures, the Chair of the University REC and/or the Research Governance and Training Manager may request copies of specific ethical release or ethical approval forms at any time whilst a project is ongoing (see below).

2.3 Post Clearance audit of projects

It is a condition of ethical Clearance that a small number of projects will be audited each year to ensure that:

applicants are using the appropriate route for ethical Clearance;

that project protocols are being followed, particularly after ethical Approval;

that any research design changes that may affect the ethical propriety of the research are being reported on;

² See University Website at: <http://www.tees.ac.uk/sections/research/governance/integrity.cfm>

³ See Guidance from UK Research Integrity Office: <http://www.ukrio.org>

that proper checks and balances are being made across the University to ensure legal compliance.

The audit should have taken place *by the last meeting of each SREC for the academic year* in question and will be overseen by the Chair of each SREC, and the Chair and the Secretary of UREC. Projects selected for audit and the results should be reported on as part of each SREC's Annual Report. It is expected that the projects audited will be selected from *the full diversity of levels*, including staff projects, and of both Release and Approval routes.

All projects selected for audit will be reported on as part of the UREC Annual Report.

3 Implications for the Assessment Process

- 3.1** A criterion for submission for Final Year Undergraduate or Postgraduate taught dissertations/projects is obtaining of ethical Clearance. *Failure to complete such procedures will invalidate submission for assessment.*

- 3.2** Final Year Undergraduate or Postgraduate dissertations/projects which commenced with ethical Clearance but for which contact between supervisor and student ceased during preparation *cease to be ethical* and will *invalidate submission for assessment.*

- 3.3** Assessment Board regulations must reflect the above.

4 GOOD CONDUCT IN THE USE OF THE INTERNET IN RESEARCH

4.1 Purpose

This section provides guidance specifically on the use of the internet for general research purposes in order to minimize risks posed by the internet environment and ensure best practice is observed.

Because of the nature of the internet it is possible that uncontrolled experimentation may result in exposure to and/or encouragement of criminal activities such as :

- *Breaches of the Computer Misuse Act*
- *Breaches of the Data Protection Acts*
- *IPR violations (e.g. Copyright)*
- *Disturbing or illegal images (e.g. Paedophile materials, terrorist images)*
- *Grooming activities*
- *Fraud (phishing, 419 scams, auctions etc.)*

Schools may wish to consider the development of additional guidance that addresses specific discipline-based risks not addressed in these notes of guidance.

All researchers should be familiar with the University's 'Guidelines for Good Conduct in Research', February 2003 (1), Research Ethics Policy & Procedures, Sept 2005 (2) and Computer Regulation Documents (3) and ensure their research activity adheres to these established guidelines and procedures.

This guidance applies to all members of the institution involved in research. This will include staff and undergraduate and postgraduate students. It also applies to those who are not members of the institution, but who are conducting research on the institution's premises or using the institution's research facilities.

4.2 Risk to the university's computer network

Any activity which may expose parts of the University computer network to risk of infection or attack must be approved by ICT systems.

4.3 Solicited data

Collection of data through the internet needs to be carefully managed to avoid unnecessary risks to the reputations of the researcher and/or the University or to the quality of the research results.

4.4 Bulk email

Generally, mass e-mailing should be discouraged as it can be perceived as activity akin to "spamming". Where questionnaires are to be distributed by e-mail, researchers should carefully target their subjects and requests permission from the subjects before the questionnaires are distributed. The precise nature of the study should be clearly explained in

the initial contact and parameters such as expected time to complete the questionnaire/interview should be given. Where research supervisors are aware that several such exercises may be conducted, a register of participants should be maintained and used to ensure that no participants are being targeted too regularly or asked to participate to such an extent that they may consider the researchers to be a nuisance.

4.5 Newsgroups and chatrooms

Newsgroups and chatrooms should be considered a form of “bulk e-mail” with the added complication that it is not possible to identify all recipients or the originators of the messages posted in them. Furthermore, newsgroup users tend to form self-selecting groups with a bias toward particular interests or opinions. Data collected as a result of newsgroup usage is likely to be strongly biased as a result.

4.6 Web-based questionnaires

Broadcast invitations to participate in an unsecured web-based questionnaire can result in skewed results, as for newsgroup participation. Furthermore, it is difficult to ensure that each respondent is only completing the questionnaire once. If web-based questionnaires are to be used they should be constructed in such a way that participants can only access the questionnaire after an appropriate invitation and can only complete it once. Provision of such a mechanism introduces issue of Data Protection in that the respondents may become individually identifiable. Care should be taken to dissociate identity verification mechanisms from gathered data unless it is essential to the study.

4.7 Observation

In order to monitor illicit activity using electronic communications, the observer must be, albeit to a limited extent, a participant in the activity. That is to say that, at the very least, they are likely to be required to create a user identity which can be used to log in to the communications system under observation.

4.8 Use of a ‘user identity’

Because a user identity can be traceable, it is inappropriate for an observer's “main”, “personal” or “official” user identity (e.g. University issued e-mail address) to be used for this activity. Instead, a disposable identity should be created for the duration of the research.

4.9 Use of computer equipment

Any computer equipment to be used for observation purposes should be dedicated to this task only, and only be accessible by the observer(s) in question. This avoids issues of accidental deposition of unwanted material on publicly accessible machines. Where the observer believes there is a possibility, no matter how slight, that they may encounter material which others would consider objectionable, steps must be taken to ensure that such material cannot be viewed by those not involved in the research.

4.10 Use of servers

Any servers connected to the University network and visible to users outside the research team must be carefully managed and constructed to avoid enticement and/or encouragement to commit criminal acts or acts in violation of acceptable use policies and agreements. Information presented on web pages/file servers etc. must comply with appropriate legislation and be factually correct. It may be necessary to include information about the purposes for which the server is operating and provide further details of the research.

4.11 Observation of criminal activity

Where the research may require observation of obvious criminal activity (e.g. Paedophile grooming, fraudulent auction sales etc.), risk assessment is essential. Participation and/or authorisation by appropriate law-enforcement bodies may be required, as may psychological assessment of the observer. Observed activities which will cause termination of the study must be clearly defined and adhered to. Observers must not participate in, or encourage subjects to develop criminal activity in any way.

Throughout the observation, an accurate contemporaneous log must be maintained. Appropriate rest periods should be scheduled. The observer must cease observation if he/she becomes concerned by any activity which has been observed.

4.12 Internet-originated references

Use of Internet-originated references should be treated very carefully. It must be remembered that the Internet is a public medium and that anyone with access to the appropriate technology can publish anything they wish without it being subjected to independent verification. Before a reference is accepted as being appropriate for citation, the researcher should take steps to ascertain the reliability of the source material. For example, an online journal or online version of a print journal can usually be considered to be as good as a print journal only when its editorial and review policies are compatible with the usual standards expected of a reliable academic publication. Some Community built information sources may be considered unreliable because of the way in which any user of the service can amend any existing data, or contribute new data without independent review or verification.

Research Ethics Guidelines

Teesside University has a set of principles for the ethical conduct of research as agreed by the University Research Ethics Committee (UREC). Each principle encapsulates a key idea or ideas of research ethics. When submitting research proposals for either ethical Release or ethical Approval, as set out in the preceding Procedures, these principles should form the basis of the ethical issues that will be considered. These Guidelines will provide an extended gloss on each principle as a way of giving detailed information and clarification of the key ideas of research ethics and so assisting in the consideration of the ethical issues.

Principle 1

Harm to research participants must be avoided: the protection of the dignity, rights, safety and well being of all actual and potential participants, researchers, non-participating members of the public, and the environment takes precedence over scientific, or any other, considerations or interests.

Principle 2

Research should be designed, reviewed and undertaken to ensure adherence to the highest standards of quality, integrity, ethical propriety and governance, and legal compliance.

Principles 1 and 2 are broad defining principles of research ethics. The first principle is that harm in all its forms should be avoided; the second a statement about the standards to which all research should aim in its scientific or scholarly quality and the way in which it is conducted. This also includes the levels of compliance required by all involved in research, research management, and research dissemination.

Principle 1 links the avoidance of harm to the interests of science and scholarship. A basic starting point in research ethics is that the aims of research for achieving scientific or scholarly knowledge are of secondary importance to the avoidance of harm. This does not mean that research methods which may involve a significant degree of risk would not be allowed to occur, but that consideration of such risks should form a part of research. Such consideration is an essential part of the scientific and scholarly enterprise and cannot be considered trivial. The critical *ethical* point is that advances in scientific or scholarly knowledge cannot be obtained through methods which will inflict harm. This involves a judgment about the value of knowledge vis-à-vis the value of protecting dignity, rights and well-being of those involved in the obtaining of new knowledge. As a starting point, this seems straightforward enough. However, it is only when considering the factors involved in more detail that one sees the difficulties in making

these kinds of assessments, whether as a researcher or as someone tasked with reviewing research proposals for potential ethical issues involving harm.

One difficult point is that because research ethics involves making judgments about value, then it is likely that different aspects of the research process will be valued by different parties in different ways. For instance, a scientist with a stake in finding a cure for a certain disease may place highest value on the successful discovery of a cure and so, in their judgment, the discovery of a cure is the priority. If such a discovery involves high risk research on human subjects then that, in the scientist's judgment of value, is an acceptable risk taken in order to discover a cure. However, such *scientific* discovery also involves an *ethical* dimension and it is here that things get complicated. Are we prepared to accept that there should be no ethical considerations in the obtaining of new and important scientific knowledge? Or do we think that such scientific knowledge has ethical limits? Would it, for instance, be acceptable to cause harm to a small number of research participants if that research successfully discovered a cure for a disease from which millions might otherwise suffer or die?

In research ethics this is at the very core of the problem of assessing risk: it is always assessed in tandem with an assessment of the potential benefits of the outcome of the research. *Risk is always weighed against benefit*. The judgment that needs to be made involves weighing up the value of the outcomes against the risks involved in discovering them. If it is determined that the risks involved in discovery are too great –ie: that a significant number of human subjects have a high chance of being harmed by taking part in the search for the cure for a disease — then greater value has been placed on protection of the research subject than on the possible discovery of a cure. In other words, it is not a natural assumption to make that potentially preventing disease in millions of people is an acceptable reason to actually cause harm to a small number of people participating in the research; nor is it self-evident that such a potential outcome is an obvious 'good'. This is not a scientific problem as much as an ethical one. The difference between these two views demonstrates the conflict between two influential ethical theories, that of *consequentialism* and *deontology*. It is also an instance of a conflict of values typical of any complex ethical issue. In research ethics such conflicts are prominent as well.

In order to grasp the difficulties in making judgments about the ethical propriety of research it is only necessary to confront one's own valuations of particular kinds of research activity, to think of such research not only in terms of its contribution to knowledge but also in terms of its wider social implications. The weighing-up of different kinds of values in such an exercise demonstrates the complexity of thinking ethically about research. Knowledge may be valuable

for its own sake (*intrinsically* valuable) or it may be valuable because of something else that it accomplishes, such as curing a disease (*extrinsically* valuable) but if in either case a human person is harmed, the question arises as to what value has been placed on the human person involved in the research which seeks either form of knowledge. This is a question about *means and ends*. If a person is harmed in the search for a cure for a disease, then the person has only extrinsic value in relation to the cure and has become a means to an end judged to have greater value. But if the justification for seeking a cure is that it will cure *people*, then the logic of the ethical decision making seems a little awry. If the person so harmed were themselves a potential beneficiary of the cure, then things are more awkward still. So in research ethics the weighing up of risk against benefit has to take into account the means used to obtain certain ends, regardless of how 'good' or valuable such ends might appear to be. In research, the means are the *methods* used and the ends are the *potential outcomes* of the research. Careful consideration of the relationship between means and ends in research ethics involves a judgement of *proportionality*. This relation bears as much importance in ethical terms as the relationship between methodology and knowledge production does in scientific and scholarly practice.

It is important to note that in research ethics proposals we are dealing not with actual occurrences but with *potentials*, *possibles*, and *hypotheticals*. There is no guarantee that in exposing research subjects to harm that discovery of a cure will ensue; neither is it certain that risky methods of research will result in actual harm to research participants. It is because research ethics deals with potentials, possibles, and hypotheticals, that judgments of value are both complex and difficult to achieve in general terms. This is a major reason why judgments about research ethics are made by committees rather than by individuals. Committee decision making involves different points of view and negotiation of different sets of values. In order to sift through the various options in making decisions, certain principles common to research ethics form a basis for what is or is not acceptable, and assist committees in reaching agreement about the ethical propriety of proposed research. Teesside's principles form that basis for ethical review at the University. As such they form a standard of ethical research.

The assessment of what would count as a 'harm' against a research participant is itself highly complex as indicated by Principle 1, which states that such harms could take place against "dignity, rights, safety and well being". For instance, harm could occur in a physical way to a person, such as injury or even death. However, a range of other harms may result from research which are less easy to predict and manage through risk assessment. 'Dignity' is particularly complex in this regard. Likewise, psychological harms such as emotional distress

are common risks in certain kinds of social science research. However, unlike physical harm risk assessment determining what is probable, possible, or what degree of harm could occur as psychological harm is very difficult. Whilst it may be possible to manage the physical environment effectively and put in place plans to ensure the physical safety of a person --such as is common in institutional actions under Health and Safety legislation --such management is difficult to achieve with psychological harms. The main reason for this is that the predictability of what may affect a person psychologically will vary widely between persons: what may affect seriously one person may not affect another at all.

This is one of the major reasons why obtaining valid informed consent (see Principles 3 and 4) from potential participants is so important, as it allows for a person to decide for themselves what may or may not be harmful for them based on their own self-understanding. This has some important consequences for how consent is dealt with. This also points to what is most difficult in all risk assessment: the assessment of harm is always also a *perception of harm* which can change significantly with individual experience and which has a highly subjective component. Different individuals -- including those who make assessments formally on committees and in risk management -- have different perceptions of harm. When the degrees and different varieties of harm are also included in the assessment of harm, it becomes clear that this is a complex area which requires careful reflection in order to make proportionate and effective judgements about what is or is not acceptable in research. It is insightful to compare a range of types of harm by setting them out across three domains -- the physical, the psychological, and the social -- into a typology which shows which harms affect which kind of agents:

<u>DOMAIN</u>	<u>AGENT</u>	<u>HARM</u>
Physical	Persons	bodily injury or death
	Institutions	damage to property
	Environment	pollution
Psychological	Persons	mental or emotional distress
Social	Persons	relationships; reputation
	Institutions	reputation; legal compliance

Harm to persons includes a range of parties: the persons involved could be the research subjects, members of the public involved in the research through their direct participation; or

they could be members of the public not directly involved in the research but who are bystanders. Harm could also occur to the researcher(s) themselves. In the last case, a problem thus ensues: what if a committee decides that the research proposed is too risky to the researcher themselves, but the researcher is prepared to accept this risk as part of the work? This is a tricky issue since it appears to place the freedom of choice of the researcher in jeopardy. However, it must be remembered that research does not take place in isolation and that even if an individual researcher is working primarily by themselves and is prepared to risk harm to themselves as part of doing research, there are 'knock-on' effects of actual harm occurring for which the researcher does not have freedom to decide. In most university-based research, for instance, if actual harm were to occur to a researcher (even if the researcher has explicitly accepted the risk of such harm occurring), there would inevitably be a negative impact on the institution in which that harm occurred, *regardless of whether or not the individual researcher found the risk of personal harm to themselves acceptable*. In contrast to our actions as private citizens -- such as finding the personal risk involved with rock climbing or shark fishing acceptable and going ahead and doing those activities -- research conducted under the auspices of an institution takes place in a context in which decisions about individual freedom are compromised by a variety of legal duties. Issues which arise here often involve insurance and indemnity for which the institution will offer liability protection to individual researchers. As will be detailed further below, individual researchers' liabilities are lessened by working within an institution, but such protection is offered at the cost of a certain amount of freedom to act as one would like. (See *Liabilities*, page 49 1c).

Another complex issue about harm is that the assessment of what is potentially harmful depends on the perception and assessment of hazards. As mentioned above, much of this depends upon *subjective* perceptions about what may or may not be harmful and it is one of the most difficult things upon which to base judgments about risk. Fundamentally, *a risk is a potential harm*. Managing risk is about lowering the potential for actual harm to occur. Therefore, in assessing risk we must look at *real* and *perceived* risk. Research is inherently risky, since it involves discovering or finding out things we do not already know and it may have results we cannot anticipate. One possible outcome we cannot anticipate is something happening which causes harm. Assessment of risk involves looking at the probability of harm occurring and the extent and severity of harm should it occur; alternatives to risk-involving actions are explored. In research ethics, risk assessment directly involves the persons who would be exposed to risk, by asking them to decide on whether or not to participate in activities which are risky based upon adequate information about those risks and upon their own self-understanding. They can then choose to accept those risks by consenting to participate.

Consent to participate in research is primarily a form of legitimising actions which are risky to participants, but decisions to act riskily are balanced against risk managing actions being taken during the research to minimise the occurrence of harm. It is not sufficient simply that a research participant consents to the risk -- or that a researcher finds a risk to themselves 'acceptable' and thus implicitly consents to that risk -- unless actions are also taken to minimise the risk itself during the conducting of the research. This is why risk management and the assessment of ethical propriety are so bound up with consent. This has a range of important factors to take into account which are covered in Principles 3 and 4.

Principle 3

Researchers and participants must normally be informed as fully as possible about the purposes, methods and intended possible uses of the research, what their participation in the research entails, and what risks and benefits are involved. This information should be accurate, clear, and easily understood by the potential participant, who should have the capacity to understand what is involved in their participation. Research proposing variation from this principle may be approved but only in very specific contexts in which the lack of proper information must be justified by the value of the research.

Principle 4

Research participants must consent to participate in a voluntary way, free from any coercion, undue influence, or manipulation. Use of inducements to encourage participation must be carefully monitored.

Consenting is matter of agreeing to something or authorising something, the lack of which would render an action unethical or illegal. It legitimises actions which could risk the welfare of participants or involve invasive procedures. A patient gives their consent before being touched physically during medical treatment: without this consent, the physical contact would be illegal. A similar rationale extends to the ethical considerations in gaining consent, although there are discontinuities between the legal and ethical dimensions of consent.

Wherever there is physical contact between researcher and participant the legality of actions are governed broadly by similar factors to those that would apply in medical treatment: touching a participant physically, administering substances or interventions, or putting participants under duress, without gaining consent to do so, is illegal and would constitute criminal assault or battery which, in addition to criminal punishment of a fine and/or imprisonment, could lead to a civil claim for damages by the participant. Importantly, in establishing a claim, participants would not need to prove harm was intended and punitive damages are available for these types of offences.

There are good reasons to believe that the legal implications for lack of valid consent in research cases would actually be harsher than those imposed in medical treatment situations. This is because in medical situations there are clear benefits which directly accrue from the treatment for the patient and the intent of the medical practitioner is clearly aimed at benefiting the patient. In research this relationship is not obvious: the possibility is that research done without valid consent from participants with whom there is physical intervention would have clear criminal liabilities for the researchers involved.

In research where there is no physical contact as such, the position is less clear. Regardless, gaining consent is a way of ensuring that interaction with participants is legal even in situations where the legal position is less defined, such as in social science research. *It is almost always ethically inappropriate* regardless of the legal position *to proceed with research on or with human participants who have not explicitly given their consent* to what will occur during the research participation.

In order for consent to be valid ethically, it must satisfy three conditions: those of a *voluntary, un-coerced decision*; made by a *sufficiently competent person*; and *on the basis of adequate information and deliberation*. To be valid, consent must be:

- Informed - on the basis of adequate *information*
- Voluntary - *un-coerced* decision
- Competent - made by a person having the *capacity* to consent

You will often see consent referred to in documents as 'informed consent' which is unfortunately a little misleading. Certainly, consent must be informed to be valid but it is still possible to have consent which is informed which is not valid. For instance, if undue persuasion was involved in decision making by a potential participant about information previously given to them, the 'informed consent' *is not valid*. It is better to think of consent as linked primarily to validity. 'Valid consent' includes the informed component but links this information to both voluntariness and competency. It also encourages researchers to think of information-giving as only one strand of the consent process which also involves other equally important factors. In other words, simply giving information to potential participants does not absolve researchers of ethical responsibility towards them. By thinking of consent as linked primarily to validity, the temptation for a researcher to think that they have 'done ethics' (ie: got it out of the way) when they have given a participant information is lessened in favour of a holistic view of ethical research as a process which is a part of professional and contemporary thinking about research practice. Moreover, for the information to constitute *valid* information, it must fulfil certain conditions itself.

Informed criterion of consent: *giving information*

'Informed' consent means that consenting is based on the provision of information to the person from whom consent is sought. There are two main aspects to the providing of information which are paramount. Firstly, that the information has a certain *quality* to it; secondly, that the information is *understood* by the person who is being asked to consent. These two factors are the main issues. The format of information and all other considerations are secondary to achieving the end of *understanding* by the person giving their consent on the basis of information which provides certain essential details about the research. In many cases, the information given will be of a formal nature but formality is not necessarily a guarantee of achieving understanding: in some cases, it may actually be a barrier to achieving it. This will depend on *who* is being asked to consent and on the *nature* of the research. Although the appropriate kind of information will vary depending on the nature of the research, the type of information given regarding the research is usually likely to include:

- Aims of the research
- What participation in the research will involve
- Why a particular type of person is sought to take part
- Potential benefits of the research
- Potential risks to the participant
- How the participants' data will be used and how participant identities will be protected during the research and in any publications or dissemination of results

The information provided should *enable* an informed choice or decision by the potential participant about whether or not to take part. It should include research aims. An outline of research methods is also recommended if those methods are likely to raise concerns on the part of the participant during their involvement. It should normally include legal rights and safeguards provided for participants. It is always necessary to include an assessment of risks that participants might be exposed to. In most cases, it should be clear that the participant can withdraw from the research at any time; in those cases where withdrawal rights are limited to particular stages of the research, then this should be stipulated clearly allowing for consent to be given or denied on this basis. It is good practice to give information about how a project is being funded and of other interested parties in the research since some people may not wish to participate on the basis of a funding source or if the information gained will be used by another interested party with whom they have a principled disagreement.

Ensuring understanding: This is the most important aspect of the consent process. Without the potential participant understanding the information given, the whole point of gaining consent is undermined. It is also the most difficult part of the consent process: whereas the design of information is under the direct control of the researcher, the understanding of the potential participant is not. In fact, there is very little that can be done to *completely* ascertain that the potential participant has properly understood the information. However, the key idea is that *information should be designed and the process of gaining consent managed to maximise the understanding of the potential participant*. The most important task is to ensure that the information and the consent gaining process *enable* the making of a reasoned and properly informed decision by the potential participant. To ensure that such a decision is enabled, it should be borne in mind that much research is technical and that information about the technicalities of research must be understandable by a member of the public. In many cases this will mean not including technical information which most members of the public are highly unlikely to understand. All of the information given must be presented in a way that is clear to a *non expert reader*. Avoidance of jargon and highly specialised methodological issues is required, since their inclusion is likely to obscure proper understanding. Without this understanding the consent obtained from information *will not be valid*. Potential barriers to understanding are:

- Participants failing to appreciate the nature of the research
- Many research methods –such as randomisation, control groups, or placebos – are conceptually difficult and many potential participants will have an inability to understand information about them
- Giving potential participants too much information that requires a lot of reading to digest or that will simply be skipped over because it is dense
- Information that is too technical or filled with jargon
- The person is not competent to understand the information. There are different dimensions to competency, one of which is legally defined below, but in general consideration needs to be given to the ability of potential participants to grasp the information to the level required to make a reasoned decision.

Deliberation: The person must have time to deliberate. There must be the opportunity for questions and discussion if needed. It is good practice to allow *at least 24 hours* for this. Never expect a decision on consent immediately, as this could easily be perceived as undue pressure to consent which compromises voluntariness, as covered below.

Cases where informed consent is difficult or impossible to obtain

In some kinds of research, it is a possibility that giving full information and gaining consent on the basis of that information will be difficult to achieve. In such cases, *compromised information giving* is acceptable as long as it is done for justifiable reasons. For instance, in certain areas of social sciences, particularly that involving behavioural research, methodological considerations may require consent to be compromised at the level of information. Covert methods may also be justified in certain circumstances, in which *no information* is given prior to research being conducted. In such cases, justification for the research would need to demonstrate the high value of the research. The kind of deception or misinformation used would also be a factor in determining the ethical propriety of the work. In cases where covert methods are used it is usually good practice to *debrief* participants after the research in order to inform them, but obviously this is not a substitute for prior consent to involvement and it will need to be done in a sensitive way. There are also types of research which might involve giving information to potential participants which is deceptive in some way. The spectrum of compromised information could include complete fabrication to withholding of particular pieces of information upon which the research method depends. Clearly the less deception involved, the better. But in all such cases, the aims of the research will need to be such that the outcomes could not be achieved by using less covert or deceptive methods. Compromising information can therefore take the form of:

- Lying about the aims or true topic of the research and/or about what participation in the research really involves (not recommended)
- Giving deliberately misleading information in some way
- Withholding information
- Covert observation, surveillance

Covert observation or deceptive participation on **online forums, social media**, or other **internet-activity** is **subject to the same ethical considerations as any other form of research**. It cannot be presumed that activity online is automatically 'public' and open for use as research data. **Online surveillance is ethically problematic**, regardless of its function in providing research data. Where possible, consent should be obtained.

Voluntary criterion of consent

Voluntariness means a decision made on the basis of information given *without influences upon the potential participant which are manipulative and/or coercive* in any way. Types of influence which would compromise the voluntary character of a decision are:

- Coercion using force or threat
- Manipulation through emotional exploitation, encouraging feelings of obligation or guilt in the potential participant
- Persuasion to consent through the use of argument or appeal to the altruism of the participant

The only certain way to avoid compromising the voluntariness of a decision is to provide proper and clear information to the participant from the beginning and to refrain from using any form of persuasion after the fact. If further information is required by a potential participant over and above that given primarily, then it is good practice only to *clarify* misunderstandings of primary information and to avoid giving additional information. If such information was not provided in the primary information then further information given later runs the risk of compromising a properly voluntary decision, since it could be interpreted as a form of persuasion to participate.

Other issues which potentially compromise voluntariness would be a variety of inappropriate relationships between the researcher and potential participants. Such relationships could be between colleagues, friends, teacher-student or employer-employee, or the use of convenience sampling which relies on acquaintances. In all these cases, a feeling of obligation or pressure to participate unrelated to the research itself is likely because of a prior relationship. Financial or other incentives or inducements to encourage participation are also potentially compromising, particularly in research involving low income populations or other vulnerable people, since the appeal of a payment for participation is likely to override a proper decision to participate based solely on the merits of the research or on consideration of the potential risks to themselves. Where incentives are used, they should be used carefully bearing in mind the target group. *Any incentive used should not be proportionately related to the risk involved.* In other words, it is not ethically acceptable to balance out higher risk with higher incentive or payment. Any payments given for participation should be based on the time and convenience commitment of participants supplemented by compensating for expenses incurred.

Competency criterion of consent: *capacity*

Competency is a question of capacity. Capacity is a qualification of competency. Certain categories of persons are said to be '*without capacity*'. In such cases, there are both legal definitions and ethical definitions of capacity. For the purposes of research the following groups *do not* have capacity to consent:

- Children under the age of 16
- Persons who are unconscious, such as people in comas
- In certain circumstances, people in extreme pain or distress
- Persons legally defined as lacking mental capacity

The *Mental Capacity Act 2005* defines lack of capacity as follows:

a person lacks capacity in relation to a matter if at the material time he is unable to make a decision for himself in relation to the matter because of an impairment of, or a disturbance in the functioning of, the mind or brain

This means that a person lacks capacity if:

- They have an impairment or disturbance (for example, a disability, condition, or trauma) that affects the way their mind or brain works, and
- The impairment or disturbance means that they are unable to make a specific decision at the time it needs to be made

The Mental Capacity Code of Practice issued by the Lord Chancellor on 23 April 2007 in accordance with the Mental Health Act 2007 sets out, in assessing capacity, a two stage test:

Anyone assessing someone's capacity to make a decision for themselves should apply the following test:

- Does the person have an impairment of the mind or brain, or is there some sort of disturbance affecting the way their mind or brain works? – it does not matter whether the impairment or disturbance is temporary or permanent

- If so, does that impairment or disturbance mean that the person is unable to make a decision in question at the time it needs to be made?

Since capacity can change over time, researchers should be aware that a change in a participant's capacity may require that participant to be withdrawn from the research or his/her participation reviewed to ensure capacity to decide to continue exists.

Children under the age of 16 require *proxy consent*. Research involving children requires researchers to obtain the consent of parents or guardians. Proxy consent usually means obtaining valid consent from parents and guardians for their children to be asked for *assent* to participate in research. Because research with children (or any other research involving obtaining consent by proxy) raises both ethical and practical difficulties in ensuring that proxies are properly informed, proposals for research involving children (or other participants requiring proxies) will need to have well justified outcomes. In other words, the significant ethical concerns raised by proxy consent must be shown to be proportionate to the aims of the research; and that the aims of the research are achievable *only* by doing research with children (or other participants requiring proxies).

Principle 5

The confidentiality of information supplied by research participants, and their anonymity, must be respected except in cases where illegal behaviour is discovered. All data and other materials from and about research participants will be collected, processed, retained, stored, and disposed of, in accordance with current legal requirements.

Principle 5 covers a range of ethical and legal issues around the confidentiality of research participants, as well as addressing the issue of regulated materials used as part of research. In contrast with issues around consent where legal and ethical concerns often overlap in undefined ways, confidentiality is an area of research ethics in which there are clear legal duties as well as ethical ones. In fact, the legal duties around the protection of research participants' confidentiality is defined in several places:

- EU General Data Protection Regulation (GDPR)
- Data Protection Act 2018
- European Convention on Human Rights (Article 8) as implemented by the Human Rights Act 1998
- Common law duties of confidentiality
- Certain areas of administrative law
- NHS Act 2006 (Section 251)
- Health and Social Care Act 2008 (Section 158)

It is a legal requirement that personal data must be processed in accordance with a number of specified principles. Under GDPR data must be:

- a) processed lawfully, fairly and in a transparent manner in relation to individuals;
- b) collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes; further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall not be considered to be incompatible with the initial purposes;
- c) adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed;
- d) accurate and, where necessary, kept up to date; every reasonable step must be taken to ensure that personal data that are inaccurate, having regard to the purposes for which they are processed, are erased or rectified without delay;
- e) kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed; personal data may be stored for longer periods insofar as the personal data will be processed solely

for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes subject to implementation of the appropriate technical and organisational measures required by the GDPR in order to safeguard the rights and freedoms of individuals; and

f) processed in a manner that ensures appropriate security of the personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organisational measures.

Processing data consists of any of the following:

- Collecting
- Recording
- Organising
- Structuring
- Storing
- Adapting
- Altering
- Retrieving
- Consulting
- Using
- Disclosing
- Transmitting
- Disseminating
- Making available
- Aligning
- Combining
- Restricting
- Erasing
- Destroying

The culmination of the above is a legally defined responsibility to protect and preserve personal data. The protection of data also has an ethical dimension but the legal and ethical dimensions must be handled slightly differently. The legal basis upon which researchers can process personal data is linked to the University's public functions. From an ethical perspective, researchers must normally obtain the consent of potential participants in research, but that consent is not the legal basis upon which personal data is processed. Consent is for participation in research, part of which will be the obtaining of personal data.

The ethical dimension involves respecting and maintaining the relationship of trust that is established between researchers and participants. Research data is often sensitive and therefore consent to its use for research purposes involves a decision to disclose personal

and/or potentially sensitive information to researchers for such purposes. Participants have a *legal* right to the protection such personal and sensitive information and researchers have a *legal* duty to comply, but the importance of the *ethical* dimensions of the relationships thus established through consent cannot be underestimated. This becomes important when circumstances arise in which the researcher is faced with a choice about disclosing information which might compromise that confidentiality and about which the law is less clear. Questions about such disclosure will be dealt with further on.

Preserving confidentiality

Personal data that is gathered, processed, and stored to be used in research is processed by researchers as part of the University's public function. Crucially, it is at this point that all the uses to which the data will be put in the research are specified. In such cases, the data remains 'connected' with the individual participant but consent has been given for specified uses. This means that the individual in question could still be identified from the data, but that the data is sufficiently protected, stored, and disposed of, in ways that protect unauthorised access to this data. Protection of data involves a well-defined protocol about:

- how the data is stored and the security of storage
- how long it is stored
- what uses the data will have
- who will have access to the data (other researchers, institution staff, general public)
- any data sharing needs to be clear.

In practice though, many people will be reluctant to consent to certain uses of sensitive data that is still identifiable and may well not give their consent for usage in certain ways, or may refuse to consent at all. In such cases, it become necessary to work with *anonymised* data.

The use of personal data for research must always be as minimal as possible ('data minimisation'), which means that only data that is essential for the purposes of the research should be obtained; where it is possible to use data that has been de-identified with a retaining identifier in the form of a code or key – 'pseudonymisation' – this should be employed; or, as far as possible, completely anonymised data should be used.

Anonymisation and pseudonymisation

Anonymising data involves severing the connection between the data and the individual. This means that the individual concerned can no longer be identified from the data. Whilst this may

well assist in guaranteeing confidentiality for participants, the problem with achieving confidentiality through anonymisation is that this usually means that researchers will need to make compromises to work in ways in which knowing the identities of individuals from whom data has been gathered is not critical to the research. This will usually mostly affect qualitative work in which interviews or case studies of small groups are used or in longitudinal studies. A compromise position in working with anonymised data which still offers confidentiality for the participant but more flexibility for the researcher, is that it is usually possible to process and store data in such a way that it can be retraced back to a specific individual participant if needed once it has been anonymised. This is usually done by developing a coded anonymisation system in which anonymised data is coded or 'keyed' in some way allowing for previously anonymised data to be re-linked back to an individual at points during the research. Given that either full and complete anonymisation, or a form of coded anonymisation, is viable for the research being conducted, there are issues pertaining to how the anonymisation is achieved which need to be addressed:

- Access to the non-anonymised personal data in order to perform the anonymisation procedure must be strictly controlled;
- If the data is to be keyed or coded --pseudonymisation-- the data and key or code be stored separately and access to the key or code must be strictly controlled. Any other documents relating to the source of the personal data must also be kept separately.

Another issue that needs to be dealt with carefully in anonymising data is the possibility that individuals could still be identified from the data even though they are unnamed. When working with groups of participants in small numbers or with a highly specific group of participants, the data that is retained could well retain enough characteristics to allow participants to be identified even if they are not named. This possibility can be avoided by stripping out information in degrees until individuals cannot be identified; by aggregating information, such as using an age range rather than specific age; or by restricting the set of data. However, in such cases it will be necessary to look at which data sets are really required for the research and to remove specific data which would make identification possible, such as age. Often in such cases, working with anonymised data will mean compromising by not using all the data available where this will not impact negatively on the research aims. Another possibility to removing a set of data completely is to aggregate it, so rather than removing all reference to age, or using a specific age (ie: 32 year old), a *range* of age would be used (ie: between 25-25 years old). It is easy to see how in small groups, adding another piece of data to the specific age (ie: female), could very easily pick out an individual, whereas the range is less likely to do

so. Which part of the data could potentially be used to identify otherwise anonymous participants and therefore need to be treated carefully will vary depending on the nature of the group of participants and the research topic, but in most cases a workable compromise is available.

Secondary data analysis

The specific issues concerning confidentiality laid out above apply mostly to primary research in which data is gathered directly from participants who give their consent to such data being gathered and used. However, confidentiality issues reach further than primary research and are just as complex when using data in secondary analysis. In such cases, data gathered from a piece of primary research is re-used for a further piece of research. It should not be assumed that this is a less problematic areas, as rather than reducing the legal and ethical duties of researchers to protect confidentiality, secondary analysis actually *increases* the difficulty in fulfilling those duties in most cases. This is because secondary analysis usually involves *re-using* data. Unless the use of the data for secondary analysis is the *same use* as in the primary research, or consistent with it; or the use which secondary analysis now requires was specified at the time the data was collected, then *such analysis of data is illegal*. There are certain exceptions to this, e.g.

for medical research, such as epidemiology, where large data sets are re-used. The exceptions are based on a justifiable and demonstrable public interest being served by secondary usage, this case being supported by the Health Research Authority Confidentiality Group requirements for exemptions under Section 251 of the NHS Act 2006.

However, such legal duties *only apply in secondary analysis which uses identifiable personal data. Anonymised does not fall into this category. Pseudonymised data does not fall into this category as long as the appropriate safeguards have been put in place.*

Disclosure and breach of confidentiality

A potentially difficult area of confidentiality concerns not how to preserve or protect it, but situations where there may be a legal or ethical duty to *breach* confidentiality. There are two distinct categories of situations involved here:

- research which is *directly interested in* legally-dubious activity from the outset, whether that interest is criminological, investigating any area of child abuse, terrorism, illegal drugs use and trafficking, prostitution, people trafficking or other criminal behaviour
- research in which there is no *primary research interest* in any of these areas

The second category is more straightforward. Research which involves *no primary interest in criminality*, child abuse, terrorism, or illegal drugs, may *incidentally to the main focus of the research* discover that criminal activity is occurring during the process of research, or that a participant involved in the research is involved with criminal behaviour. In such cases, the participant will have already consented to participate in the research and the researcher will have begun work on the research with those participants in a research topic completely unrelated to criminal activity, terrorism, drugs, or child abuse. This means that the participant has consented to participate and as part of this consent process, the researcher has been trusted with preserving the confidentiality of that participant.

In normal unproblematic cases, the researcher would have the duty to preserve this confidentiality in all circumstances. However, in certain cases there are conflicting legal and ethical duties which either legally trump the duty to preserve confidentiality, or which provide an ethical dilemma for the researcher. It should be noted that what are or are not legal duties in the breach of confidentiality are in some areas very unclear, with certain exceptions. These exceptions are as follows:

- In all cases, if *terrorist activity* or activities connected to preparation for terrorist activity are discovered *incidentally* during research (ie: the research topic is not connected to terrorism), the researcher has a legal duty to report those activities regardless of whether the same amounts to a breach of confidentiality (if there is a breach, the researcher will accordingly have a defence). Failure to report discovery of such activities is itself a criminal offence liable to prosecution under the various pieces of terror legislation passed between 2000-2008 introduced to tackle terrorism.

- If during the course of research, other criminal activity is discovered incidentally (ie: the research topic is not connected to criminality) then whether or not there is a legal duty to report this activity is context dependent (ie: it will depend on what those activities are). If those activities involve money or assets which are the proceeds of criminal activity, then the researcher has a legal duty to report this under the Proceeds of Crime Act 2002. For other criminal activity, such as drugs related crime, the incidental disclosure to the researcher of avoidance of prosecution for a serious offence (such as murder or rape), or plans to commit such offences, then there is no clear legal duty, but the researcher may need to seek legal advice in specific cases.
- If during the course of research, child abuse is discovered and *the researcher is themselves a social services professional*, then the researcher has a legal duty to report this abuse as a professional practitioner in the field concerned with dealing with child welfare. This would apply in research which is *not* primarily related to children or in research which *is* directly focused on children. However research which is directly focused on the abuse of children or children's welfare will bring further complications which are addressed below. Researchers who are not social services professionals who discover child abuse do not have a *legal* duty to report on this discovery.

However, there is clearly the question of the researcher's *ethical* duties in such situations, which will be explored below.

Research which has *direct interest in criminality* is a far more complex area for legal compliance and ethical propriety. In such cases, the researcher enters into the research knowing *a priori* that there will be criminal activity occurring. The issue of disclosure then pertains to what *kind* of information or knowledge may well become available that may place extra duties on the researcher, or in extreme situations place the researcher at risk. Examples could be:

- Research into criminal activity in a carefully prescribed area, for which participants are recruited on the basis of their criminality, but the crime involved is relatively unserious. During the course of the research it becomes apparent that very serious crime is occurring.

- Research into crime with participants who have consented on the basis of full confidentiality, confide information to the researcher that was not of interest to the original research but which compromises the researcher and the participant's confidentiality because it involves third parties who were not known to the researcher at the commencement of the research and who have not given consent. In such cases, serious complications could also ensue if such third parties become aware of the disclosure.

Regardless, in all cases of disclosure there will be an *ethical* duty of some kind. It is the various ethical duties which present a range of potential dilemmas for researchers, as the ethical choices may involve compromising the confidentiality of research participants with whom one has established a working relationship in order to resolve a subsequent disclosure. These ethical issues become even more difficult when working with fore-knowledge of criminal activity, such as in criminology research, where the researcher may need to plan for such eventualities by planning consent in such a way as to reduce the possibility of being put in a compromising ethical situation with participants for whom a relationship of trust has been established and upon which future research may well depend.

Regulated materials

Certain forms of research materials are also regulated in a variety of ways:

- Research which works with *human tissue*. Human tissue includes body parts, blood, semen, saliva, and other bodily fluids. Human tissue does not include fingernails or human hair. Regulated by the Human Tissue Act 2004
- Research which seeks to analyse DNA for identifiable data. Regulated by the Human Tissue Act 2004
- Research which works with radioactive or other dangerous materials or in dangerous environments. Regulated by Management of Health and Safety and Work Regulations 1999 (Regulation 3 Risk Assessment); Ionising Radiations Regulations 2006; Hazardous Waste (England and Wales) Regulations 2005; and Health and Safety at Work Act 1974.

Tissue which is regulated can only be collected, processed, retained, stored, and disposed of in specific ways. Institutions must be licensed for human tissue to be used in other ways. At the time of these Guidelines being issued (October 2010), Teesside University does not hold a Human Tissue License. Any human tissue, including blood or bodily fluids, must not be stored for longer than 48 hours without specific consent having been gained for doing so, and in such cases the uses to which tissue will be put are *strictly defined in law* and cannot be compromised. Any research which may *incidentally* involve human tissues is also affected, if tissue is collected or stored in any way, even if incidental to the purposes of the research. The extraction of DNA from human tissue for non-identifiable purposes is allowed as long as consent has been gained for such work. Other uses for the purposes of DNA analysis are strictly regulated and are illegal unless conforming to specific parameters. The use of tissue for purposes not strictly defined as a specific exemption from regulation, when used in an institution without a license, is illegal.

Work with radioactive materials is also regulated. Research using other dangerous materials such as chemicals and research conducted in dangerous or risky environments needs to undergo risk assessment and comply with the Health and Safety at Work Act 1974 and associated Regulations, much in the same way as other sorts of activities within the course of employment. Risk assessments form part of ethical Clearance procedures and paperwork associated with such assessments needs to be included with ethical Release or Approval forms.

Principle 6

The independence of research must be clear, and any conflicts of interest or partiality must be disclosed. Publication of research results must be done fairly and with the public good taking priority over private or personal interests.

Conflict of interests

A conflict of interest is any involvement between the researcher(s) and other parties, such as funding sources or external agencies to which reports or other materials will be divulged, which if undisclosed could be interpreted as compromising the researcher(s)' objectivity. For instance, if a project looking at the effects of childhood obesity were funded even in part by a fast food organisation and such funding were undisclosed, then a conflict of interest between the funding organisation's interests and those of objectivity of outcome could result. In such cases, involvement of all funding bodies with an interest in the outcome of the research should be disclosed to ensure transparency. This disclosure would normally be included in information given to potential participants enabling them to decide on whether to participate, but such disclosure should also be included in any reports or publications resulting from the research. If in doubt about a potential conflict of interest, then always disclose. *If disclosed a conflict of interest -- in the sense defined above -- cannot arise.*

Publication ethics

There are two main areas of concern in the ethics of publication:

- The duty or requirement to publish research
- The transparency and accreditation of authorship and involvement in research which is published

The first area concerns whether or not research results are published when there are reasons why certain parties may not find this desirable. There are two possibilities to this. Firstly, the *researcher themselves* may not find publication of research desirable if the results conflict negatively with previous research or prove to have other negative consequences. This is a question of the duty of researchers to publish research if it is of sufficient quality or interest to others, regardless of their own personal interest. Secondly, there could be other parties –such as funding sources- for whom the results of the research are unwelcome. In such cases, pressure could be placed upon a researcher to withhold publication altogether or to censor the publication in order to make it appear more positive. In both cases, it is unethical to not publish research if the quality of the research would be of a standard high enough to pass

through peer review or other quality control and editorial processes, if the results of the research would have an impact on the public good. It should also be noted that changing the results or outcomes of a piece of research significantly in order to censor or present results in a more favourable way is also a form of research misconduct akin to fabrication or falsification of data which carries severe consequences if discovered.

Authorship is a complex area ethically. The criteria for crediting authorship on papers are as follows:

- Any party who has contributed to the research itself is considered an author. Such contribution includes data gathering or generation, analysis or interpretation, and drafting, editing, or proofing text used in the publication. It does not include securing funding or any other support functions, such as facilities. These contributions are not authorship related. They can be credited but not as part of the authorship credits. The difference is between claiming *authorship itself* and the authors *acknowledging* the input of others in achieving funding or providing facilities. Failure to give credit for authorship according to the criteria above is unethical, as is deliberately weighting accreditation so that an impression is given of less input to a project than actually occurred.
- Any party who has not contributed to the research as stipulated above in either authorship or other actual support function and whose name is included as a favour, even if reciprocal, is not an author and such inclusions –whether common tacit practice or not – are unethical. Again, this is a case of wishing to *acknowledge* rather than give a credit for authorship itself. ‘Ghost’ authorship in research publication brings the notion of academic authorship into disrepute.

It should be noted that the question of questionable authorship credits in publications published in major international journals is increasingly considered a form of research misconduct by journal editors and the professional bodies which represent them. Researchers who engage in such practices put the reputations of themselves and other colleagues at risk. It should further be noted that an author of work, if in the event he/she is no longer the proprietor of the work (ie: he/she has assigned it over to a 3rd party), is entitled to moral rights under the Copyright Design and Patents Act 1988 (section 77) which, inter alia, grants the author the right to be recognised for his or her work. Therefore, this should be borne in mind when attributing work.

Potential legal liabilities of researchers

1) Harm occurs to participants, property, resulting in claim of *negligence*

- a) Negligence involves lack of proper process of risk assessment and can be intentional or reckless
- b) Going via institution's REC procedures constitutes protection
- c) Research conducted without proper procedural accountability severs the protection of the institution's indemnity arrangements and leaves the researcher open to personal liability for negligence. In practice, this means that if a researcher chooses not to apply for ethical Clearance, using either Release or Approval, and a claim is made against them by a participant for any reason, then the researcher may be personally liable. This may also apply in cases where a researcher has applied for ethical Clearance but who chooses to ignore requirements placed upon the research protocol by the REC in order for it to proceed; or who subsequently changes the research design previously approved in the protocol submitted to an REC without notification.

2) Lack of valid consent

Researcher may be exposed for criminal and/or civil assault or battery which may attract a criminal punishment of a fine and/or imprisonment and a civil claim for damages.

Potential legal liabilities for data breaches

Liability for the institution under the Data Protection Act, which attracts criminal liability, financial fines and potentially financial claims for damages.