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1 Philosophy of research ethics

Plato (427 - 347BCE) was a student of Socrates and in his writing transmits Socrates' teachings. The main thrust of this comes in his middle and later periods, the Republic being the most important.

Plato highlights virtue which he equates with knowledge, to be virtuous is to know the good which is changeless, immaterial, transcendent and absolute.

Aristotle (384 - 322BCE) was Plato’s pupil. His writings on ethics have as their basis the search for the chief human good. This, he argues, comes from the ethical virtues that come from human reasoning. Each virtue is the pivotal point between excess and defect.

Virtues are not just rules by which we live but should encompass the whole of a person’s philosophy of life and determine concerns, desires, emotions and perceptions of virtually everything as well as governing the actions that a person takes.

1.1 Ethical codes

These principles have been the foundation for ethical codes since then and have been updated to take into account developments in the world. One of the best examples of this is the medical codes of practice. There have been medical codes of practice from ancient times, the most famous of these being the Hippocratic Oath, emphasising the need for the practitioner working to the highest possible standards and with total confidentiality in the care of patients. Contrary to popular belief, there are few medical schools where pupils take this or any other medical code of practice oath!

Codes of medical practice are needed for many reasons, although many would argue that medical ethics involves no more than applying good manners and that anyone with high moral principles does not need rules. This, however, takes an over-optimistic view of human nature. This was seen in the experiments carried out by some doctors in Germany and Japan during the Second World War, which lead to the trials of 1947 and the writing of the Nuremberg code.

Another important reason for having such codes is to regulate the research that is being carried out so that it protects the participants from overzealous practitioners who are willing to overstep the limits in order to strive for cutting edge results.

Other important codes that have emerged in recent years are:

- The Declaration of Geneva (1948 & 1968) which brought together many of the previous declarations.
- The Declaration of Sydney (1968) which specifically deals with the issue of death, especially in the field of transplants.
- The Declaration of Tokyo (1975) is a declaration on torture and other cruel, inhuman or degrading treatment or punishment.
• The Declaration of Hawaii (1977) dealing with psychiatric medicine.

The codes used in medicine have been further developed outside of the medical field to provide structures for professional self-regulation. Ethical issues come into almost all professions: medicine, law, nursing, science, education, social work, engineering, counselling, architecture, journalism, computer science, etc.

1.2 Ethical issues

The role of a professional is to be a trusted adviser by virtue of their professional knowledge. But given the nature of certain professions, ethical issues arise. Primarily, the professional is often held in high regard and trusted by clients and public because of their (perceived) knowledge. When a professional asks a client or member of the public for their consent to do something the client can feel unable to decline. Or the professional may believe it is not in the best interest of the client to obtain their consent and that the decision to carry out research should rest with the professional.

Many professionals also face the ethical issue of confidentiality. It may be necessary for the professional to gain information from the client that the client would not be happy to disclose to others.

There are the ethical issues of truthfulness; results that may emerge from research may not be known to the client, would keeping the results from the client be for the client’s good? Does this justify actively deceiving clients?

1.3 Ethical approaches

There are a number of ethical approaches that determine the way we live, work and do research.

1.3.1 Utilitarianism

The most commonly held approach is utilitarianism. Utilitarianism is attributed to Jeremy Bentham (18th &19th Centuries). It seeks to find the greatest benefit to society from our actions. Bentham’s motto was “the greatest good for the greatest number”.

This is a very democratic approach to ethical decision making, voting and allowing the majority to decide the outcome. It assumes that people are generally to be trusted to make good ethical choices.

But there are limits: the majority of people could make choices that are not ethical.

1.3.2 Cultural relativism

Everything is relative.

This is attributed to Franz Boas (early 20th Century). It asserts that whatever we do should be understood in terms of the culture in which we live and work. What might be ethical in one culture might be unethical in another. Acceptable behaviour in one group might be unacceptable in another.

There are limits to this approach: basic human rights might over-ride cultural relativism.
1.3.3 Egoism

If it feels good do it!

Egoism tries to answer the question: “What will make me feel the best?”

Although not appearing ethical on the surface, many decisions based on egoism can indeed be solid ethical choices. Egoism is probably the most used ethical approach for people.

When faced with an ethical dilemma, many people consider what decision would likely be in their best interest and thus benefit them in some important way.

But egoism can be masked by altruism; there may be motives behind why we make certain ethical decisions.

There are limits to this approach: what is in the best interest of yourself, may not be in the best interest of others.

Doing what makes you feel good will clearly not be the right thing to do in all situations.

1.3.4 Absolute moral rules

The word ‘absolute' in an ethical situation refers to a rule which maintains obligatory force under all circumstances, it allows for no exceptions.

There are limits to this approach: we may all try to tell the truth at all times as our absolute moral rule, but are there times when it is necessary to not tell the truth?

1.3.5 The social contract

This approach recognises that we were all born as free-thinking individuals, but that our ethical actions are determined by the government, laws and rules of the society in which we live.

In order for everyone to live/work happily within any community we have to both formally and informally understand how we behave with regard to the others that live/work in that community.

Laws and rules are based on this concept; structure and guidelines are necessary to ensure safety and order, and there are structures in place to punish those who do not abide by them.

There are limits to this approach: people may disagree with particular social contracts, we may think that some rules are unfair.

1.3.6 Rights approach

This takes the view that each individual has dignity and is worthy of respect. The principle states that an action or policy is ethical if it advances or protects moral rights.

There are limits to this approach: as long as you harm no one, do you have the right to think and behave how you wish?
1.3.7 Justice approach

What is fair?

Justice looks at the fairness or the unfairness of the actions of individuals in the distribution of benefits to a group: treating others in a fair, reasonable and respectful manner.

There are limits to this approach: research has shown that people usually find attractive people more intelligent, wise, talented, and sophisticated. An attractive person is more likely to be offered employment that an unattractive person. Is this fair? Is this just?

What exactly is meant by justice?

1.3.8 Common good approach

This is the ethical action that contributes most to the welfare of everyone. What is in the best interest of the community is seen as being the most ethical decision.

There are limits to this approach: not everyone will agree as to what is the common good. It could be in the best interest of society that everyone eats a healthy diet, doesn’t smoke or drink and always practices safe sex; others would argue that this takes away an individual’s freedom to choose.

1.3.9 Virtue approach

There are a number of personal characteristics and qualities that we value and should work towards achieving, including: honesty, integrity, responsibility, compassion, politeness, thoughtfulness, kindness, etc.

There are limits to this approach: how can we all agree on the list of virtues by which everyone should live?

1.3.10 The humane community approach

This is a vision of society as a community whose members work together for the goals and values that they hold in common with each other.

Almost every decision we make has ethical implications and we are faced with making both ethical and unethical decisions every day.

1.4 The basis for all ethical decision-making

These five principles come from several thousand years of moral philosophy and ethics.

- Respect: treating others with attention, esteem and consideration.
- Responsibility: needing to be accountable and following through on obligations, promises and commitments.
- Integrity: following high standard of honest, justice and fairness.
- Competence: having the skills and knowledge that makes a person qualified to work in their particular profession.
• Concern: what is our ethical responsibility to those who have less than we do?

2 History of research ethics

The information in this section provides a history of ethical practice in relation to human participants. Readers should note, however, that other ethical principles relate to all research, whether or not human participants are involved.

2.1 Key milestones

The classic statement with regard to the right to self-determination is as follows:

“Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages.”

Cardoso J in Schloendorff v Society of New York Hospital (1914)

There can be little doubt that the greatest incentive to attempt to regulate research involving human subjects was provided by the revelation at the Nuremberg Military Tribunals (1946) of atrocities performed by Nazi doctors in the name of medical science.

The Nuremberg Code (which first appeared in 1947) contains a number of fundamental principles which continue to form the basic framework for much regulation of research endeavour in the modern age.

Key extracts are as follows:

“The voluntary consent of the human subject is absolutely essential.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

The experiment must be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random or unnecessary in nature.

The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.”

The Code was laid down as part of the judgment in the trial, and, building on this, in 1953 and 1962 the Medical Research Council published statements on the conduct of research. The Nuremberg principles were adopted and developed by the World Medical Association in the Declaration of Helsinki in 1964 (substantially revised in 2000), which contains the fundamental principle that, while scientific progress is an important public good, “...considerations related to the well-being
of the human subject should take precedence over the interests of science and society”.

In 1966 the first research ethics committees were set up in the United Kingdom, but it was not until 1991 that Department of Health (DoH) guidelines on Local Research Ethics Committees (LRECs) was finally published, to be followed, in 1997, by the creation of Multi-Centre Research Ethics Committees (MRECs).

Public scandals, such as an inquiry into allegations of misconduct concerning a research study in North Staffordshire (NHS Executive, 2000), served to highlight a number of procedural defects which led to the introduction of the Research Governance Framework for Health and Social Care (DoH, 2001; revised, 2005) and the establishment of the Central Office for Research Ethics Committees (now part of the National Patient Safety Agency, 2005).

In 2001, the EU Clinical Trials Directive was agreed, which provides legal control in relation to all drugs trials in the EU and of research ethics committee procedures.

2.2 The National Health Service

In the NHS, from 1991 onwards, there has been a well-established mechanism for scrutinising research – the Local Research Ethics Committee. This has been refined by MRECs (1997) and covers NHS property, staff, patients, and NHS users such as relatives and carers.

COREC (now known as the National Research Ethics Service (NRES)) was established in 2000 to bring about standardisation of procedures and forms from October 2002 onwards. Further uniformity has been assisted by the Association of Research Ethics Committees, primarily medical, but now becoming increasingly involved in the governance of non-medical research.

2.3 Local Research Ethics Committees

LRECs (established and administered by Health Authorities), Multi-Centre Research Ethics Committees (MRECS) and, possibly in the near future, Local Authority Research Ethics Committees – to which a project, dissertation or thesis proposal may, in appropriate circumstances, need to be submitted – are advised that:

“3.3. [Such committees] should consider the ethical implications of all proposals which involve human subjects, including, for example, questionnaires. All proposals will belong to one of two categories, therapeutic and non-therapeutic research. Therapeutic research carries the prospect of direct benefit to the research subject. Non-therapeutic research, whilst designed to advance scientific knowledge and therefore be of collective benefit, is not expected to give a direct benefit to the research subject. Non-therapeutic research may involve ‘healthy’ as well as ‘patient’ volunteers.

3.4. Where people volunteer to take part in non-therapeutic research, they should know that they cannot expect to derive any direct benefit from that participation. The LREC will therefore want to be satisfied that the risk to which they are submitting themselves can be justified by the expected collective benefit.”

[DoH, 1991]
2.4 University Research Ethics Committees

However, there are no nationally agreed procedures for university research - HEFCE is silent on the matter, and research (Tinker, 2001) showed that very few institutions had any, or any sophisticated, scrutiny arrangements for the social sciences. In the past few years, though, most universities in the United Kingdom have established research ethics committees to deal with policy and applications in any discipline, where human participants are involved.

A Research Ethics Committee (REC) in a university may be a central University Committee (UREC) and/or a devolved committee. The advantage of a UREC is that it is a mechanism using a structured, transparent process with University-wide standards, giving parity of treatment to all applicants. It allows for a range of disciplines to be represented and ideally includes lay members. Its disadvantages can be: a bureaucratic process, high workload; and slow response time if it does not meet frequently. A devolved system at College level may allow for greater focus on specific disciplines, a quicker response to applicant and less bureaucracy - but may lead to inconsistencies of approach across disciplines and a lack of transparency outside the College. In neither case is the REC like an NHS LREC - it is still part of the University, retaining accountability and responsiveness to the University.

2.5 Department of Health Research Governance Framework

The implementation of the Department of Health's Research Governance Framework requires that independent ethics review be undertaken of all health and social care research. NHS Research Ethics Committees are responsible for reviewing any research that involves NHS staff, service users or user-data. However, some types of research, such as surveys and service evaluations, are excluded from NHS REC review. In addition, most social care research has no connection with the NHS. Accordingly, it was recognised that for research in the social care arena, NHS RECs might not be the appropriate bodies to conduct ethics review. Thus, a national system for ethics review in social care was deemed to be necessary.

A planning group was set up by the DoH in 2006 to provide address this issue. It recommended that a central Social Care Research Ethics Committee be established for those projects which would not otherwise be subject to ethical review. The DoH is now in the process of creating this committee.

2.6 Recent updates

The DoH established a Working Group (known as the Doyal Committee) in 2004 to examine the issue of ethics scrutiny of student research projects. The report by the Working Group (Doyal Report: The Ethical Governance and Regulation of Student Projects, Department of Health, 2005) (states that “some system of systematic ethical review is essential and non-negotiable” and advocates the creation of Student Project Ethics Committees (SPECs). The point is strongly made that, while student research proposals must adhere to established ethical standards, they should not be rejected on the grounds that the projects are not likely to result in new, publishable knowledge. Nevertheless, the potential for harm to human participants in student research projects is just as real as it is in projects proposed by experienced researchers.
The SPECs would review those student proposals in health or social care involving NHS premises, staff, patients, or tissues.

As of 2008, no action had been taken by the DoH on this.

2.7 Professional associations and funding organisations

Most professional associations have now published their own ethical standards and codes of conduct. Some, such as the Royal Academy of Engineering, have developed training modules or curriculum maps to provide advice and assistance in the inclusion of ethics training in degree programs.

A number of funding organisations have published their own ethical frameworks. These provide standards for ethical review of research proposals and the composition of ethics committees.

3 Theory of research ethics

For all students and staff undertaking research involving human participants within the University, during the preparation of a project/dissertation/thesis proposal, consideration must be given to the ethical implications of the research you are intending to carry out. It is the role of the University Research Ethics Committee, and Colleges implementing procedures under delegated authority, to ensure that this aspect has been addressed to a satisfactory minimum standard before your research proceeds, and to this end your proposal must be subject to appropriate scrutiny. The intention of these Guidelines is to assist you in this task. Further information and guidance will be provided by your Supervisor and/or the College Research Ethics Officer.

Research involving human participants may consist of:

- observation;
- talking, discussion, listening, or
- physical, chemical or physiological intervention.

It is also of importance to note that research may either create records or use existing records containing biomedical or other information about individuals who may or may not be identifiable from the records or information. Protection of confidentiality, then, immediately becomes a central issue.

3.1 Theoretical aspects

Before considering the practical aspects of gaining ethical approval, it is important to understand some of the theoretical issues that underlie research ethics in relation to human participants. There are three main approaches that underpin all of our ethical thinking about research: goal-based, duty-based, and rights-based.
3.1.1 Goal-based

The first main approach to ethical thinking is the **goal-based approach**. Based on the consequentialist theory, the approach assumes that the researcher should try to produce the greatest possible balance of benefit over disbenefit. A researcher taking this approach would believe that if the intended outcome of the research is worthwhile, then the means of achieving that outcome is worthwhile. This implies that discomfort to one individual may be justified by the consequences for society as a whole. However, even if the research is itself ethical, it is of no use if the outcome is of little value; thus the outcome is as important as the process.

3.1.2 Duty-based

The second approach is **duty-based**. Your duty as a researcher is founded on your own set of moral principles. As a researcher, you will have a duty to yourself and to the individual who is participating in the research. Thus, even if the outcome of the proposed research is for a good cause, if it involves the researcher lying to or deceiving the participants in any way, then this would be regarded as unethical.

3.1.3 Rights-based

The **rights-based approach** takes a similar perspective to the duty-based approach. The rights of the individual are assumed to be all-important, thus a participant’s right to refuse must be upheld whatever the consequences for the research. This is based on the idea that we should always follow natural laws and rights. This means that our ethical responsibilities are primarily to the individual and that every human being, including you, should be respected even if this may have some unfortunate consequences.

3.2 Ethical principles and rules

3.2.1 Ethical principles

It is widely acknowledged that all research involving human participants must acknowledge and conform to four basic ethical principles of autonomy, non-maleficence, beneficence, and justice. These four basic principles are derived from the approaches outlined above. It is obvious that some of the principles derived from these approaches may be in conflict with one another, and thus some principles rate higher than others in order of importance. The principles are always binding, unless they are in conflict with other principles, in which case it will be necessary for you to justify why one principle has been chosen over the other. This is the basis of moral reasoning.

i. **Autonomy** – i.e., *respect* for the autonomy of the individual and protection of persons with impaired or diminished autonomy by the provision of safeguards against harm and abuse. The duty of the researcher is both to recognise the research participants’ capacities and perspectives and their right to make choices about whether or not they will take part in any research project. That person should also be treated so as to allow them to act in an autonomous way.

ii. **Non-maleficence** – the researcher is under an obligation not to inflict harm or expose people to unnecessary risk as a result of the research project. This is particularly important when the research participants may have impaired or diminished autonomy.

iii. **Beneficence** – the obligation to maximise benefits and minimise harm. This principle obliges the researcher to assist others to pursue their interests.
However, there may be conflict between, for example, the principle of autonomy (the right to make an informed choice) and beneficence (where part of the study involves non-disclosure to that person as it may do them harm). Paternalism occurs when a researcher acts in the belief that an individual’s views should be disregarded since it is in society’s interest to do so. If one principle is to be overridden by another, the researcher must be able to justify that decision to the satisfaction of independent scrutiny.

iv. **Justice** – the obligation to treat each person in accordance with what is morally right and proper. This principle is concerned with people receiving their due. Equality of opportunity is particularly important here, and is of particular importance when considering inclusion/exclusion criteria.

These Guidelines seek to examine these ethical principles in relation to issues which must be carefully addressed and considered by the competent researcher. Research studies are judged ethically on three sets of criteria: **ethical principles**, ethical rules and scientific criteria. The latter is often neglected, but is important since if a study design is poor or the sample size is insufficient, then the study is not capable of demonstrating anything and consequently could be regarded as unethical.

### 3.2.2 Ethical rules

The four key ethical rules are:

- **Veracity**: i.e, truthfulness or absence of deception;
- **Privacy**: freedom from unwarranted public intrusion;
- **Confidentiality**: non-disclosure; and
- **Fidelity**: in research terms, accuracy in recording and reporting data.

### 3.3 Practical application of ethical principles and rules

Researchers must apply the ethical principles and rules discussed above in every aspect of their research, from the design of the study to the publication of results. In this section we examine specific issues such as consent, confidentiality, types of participants, and other matters to be considered.

#### 3.3.1 Consent

Research carries the attendant potential to:

- i. cause harm, in the form of actual damage or disadvantage (the practical context);
- ii. ignore the autonomy of the individual (the moral context).

It is, of course, a truism to state that harm cannot be entirely eliminated from the research process, but if we insist that individuals are provided with adequate information and choice about participation, we can at least minimise the possibility of realising either of the above potentials.

Rule 1 of the Nuremberg Code (Rev.1981) emphasises the fundamental importance of consent thus:
“The person involved should have the legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the subject-matter involved as to enable him to make an understanding and enlightened decision.”

This brings the notion of informed consent into focus. In law, valid consent may be express or implied. Express consent requires an active, affirmative assertion made either orally, in writing or a mixture of both. The notion of implied consent rests on an assumption derived from conduct, e.g., the offering of an arm for taking blood pressure. In law, the minimum consent requirement is the absence of a negative, i.e., not saying ‘no’. It should be emphasised, however, that, wherever possible, active, informed consent should be sought. Even this can be an imperfect safeguard, which is why independent scrutiny of research proposals is insisted upon by the Department, and, where applicable, by LRECs. The more limited the capacity of the research subject, e.g., young children, or persons with severe mental or behavioural disorders, the more important independent scrutiny becomes. Mere passivity should not automatically be assumed to equal consent.

In the light of the above, it is normal ethical practice to provide the potential research participant with sufficient information in writing to enable them to reach an informed decision within a reasonable length of time.

Even where express consent is not required, a comprehensive Participant Information Sheet must usually be provided.

In providing the information, care should be taken to:

- give the prospective participant full opportunity and encouragement to ask questions;
- exclude the possibility of unjustified deception, undue influence and intimidation;
- seek consent only after a sufficient opportunity has been provided to consider whether or not to participate;
- as a general rule, but subject to exceptions, e.g., questionnaires, obtain from each prospective participant a signed form as evidence of consent;
- renew the consent if there are material changes in the conditions or procedures of the research.

Although a particular emphasis on informed consent should be regarded as the norm, there are some instances, particularly within the realms of the social sciences, where a blanket insistence upon the necessity for informed consent would stifle, if not totally preclude, important research into, for example, human behaviour.

Individual consent may thus be unnecessary for some research activities, such as community research, which may be quite unintrusive, for example, studies involving observation of human behaviour. Where the nature of the research is such that informing participants before the work is carried out might render the results invalid, for example, within aspects of the social and cognitive sciences such as perception, appropriate explanations must be given. Researchers must provide convincing reasons why such research should proceed without the
necessary informed consent. Researchers should not mislead participants if it is thought that prior permission will not be obtained.

Where research is to be undertaken in public places, those engaged in the research should also have due regard to religious and cultural sensitivities.

3.3.2 Confidentiality

Researchers will need to show clear evidence that:

(i) personal information will be kept confidential;
(ii) data will be secured against unauthorised access;
(iii) no individual will be identifiable from the published result without his/her explicit consent;
(iv) all data from which an individual is identifiable will be destroyed when no longer required. In certain circumstances the researcher may wish/need to retain such data beyond completion (particularly for external scrutiny purposes). Here, all relevant persons (particularly the research participant) must be made aware of the reasons for retention, and the circumstances where disclosure might occur. Written consent will be required.

Written permissions and the general principles of confidentiality also apply in relation to the medical records of deceased persons. Permission to use these must, therefore, be sought from the LREC.

DoH Guidance to LRECs (1991) provides further important detail:

“3.12. Epidemiological research through studies of medical records can be extremely valuable. Patients are however entitled to regard their medical records as confidential to the NHS and should in principle be asked if they consent to their own records being released to researchers. However, there will be occasions when a researcher would find it difficult or impossible to obtain consent from every individual and the LREC will need to be satisfied that the value of such a project outweighs, in the public interest, the principle that individual consent should be obtained. When a patient has previously indicated that he or she would not want their records released, then this request should be respected.

3.13. The LREC will need to be assured that this kind of research will be conducted in accordance with current codes of practice and data protection legislation. Wherever possible, consent should also be sought from the health professional responsible for the relevant aspect of the subject’s care. Once information has been obtained from the records no approach should be made to the patient concerned without the agreement of the health professional currently responsible for their care.”

3.3.2.1 Data Protection

The consent form will need to include a statement that the data obtained will be held securely only for the time necessary to complete the project. Data should not be stored on computers or discs to which unauthorised persons may have access. This needs to be carefully considered when using the computer at home. Questionnaires should not be returned to home addresses, as subjects may interpret this as meaning that data will also be stored at home, and will therefore
not be secure. Thus, information returned by post to the researcher should be sent to the University address.

Regard should also be had to the Principles of Data Protection as laid down in the Data Protection Act 1998, viz.:

1. Personal data shall be processed fairly and lawfully.

2. Personal data shall be obtained only for one or more specified and lawful purposes, and shall not be further processed in any manner incompatible with that purpose or those purposes.

3. Personal data shall be adequate, relevant, and not excessive in relation to the purpose or purposes for which they are processed.

4. Personal data shall be accurate and, where necessary, kept up to date.

5. Personal data processed for any purpose or purposes shall not be kept for longer than is necessary.

6. Personal data shall be processed in accordance with the rights of data subjects under this Act:
   a. To have access to one’s own personal data;
   b. To prevent processing likely to cause damage or distress;
   c. To prevent processing for the purposes of direct marketing;
   d. To prevent decisions being made on the basis of automatic processing of personal data.

7. Measures shall be taken to prevent unauthorised or unlawful processing of personal data and against accident loss or destruction of, or damage, to personal data.

8. Personal data shall not be transferred to a country or territory outside the European Economic Area unless that country or territory ensures an adequate level of protection for the rights and freedoms of data subjects in relation to the processing of personal data.

Once your research has been completed, confidential data relating to subjects should normally be destroyed and assurances should be given to this effect. However, in certain instances, there may be legal requirements concerning the length of time during which data must be retained and you may need to give careful consideration to this. Further, if your project/dissertation, etc., forms the basis of a published research paper, authors may be asked by publishers to provide the raw data at any time within a prescribed period (e.g., five years in the case of *The Lancet*).

Issues may arise concerning the ownership of the data. As a general principle, data contained in a project/dissertation/thesis submitted in partial or total fulfilment of a degree award of the University belongs to the University, and relevant advice and permissions may, therefore, need to be sought.
3.3.3 Types of participants

Two general groups require initial consideration.

3.3.3.1 Healthy volunteers

It is unlikely that healthy volunteers will benefit directly from the research undertaken. They may, therefore, be more difficult to recruit. In relation to such volunteers, the following points should be noted:

- there must be no pressure to volunteer, e.g., arising from some obligation;
- recruitment should be public, i.e., by appeal to a cohort, rather than by individual, private recruitment;
- the term ‘healthy’ requires specific definition for the purposes of the study.

You may be seeking to conduct research involving participants who are members of professional groups. Members of professional groups are known in the sense that their names appear in a public register. It is considered that it is the responsibility of the researcher to acknowledge the source of the name and address of such members in a covering letter which should accompany any questionnaire, and further, that the researcher has the responsibility of distinguishing the personal opinion of the professional participant from institutional policy and particularly, to protect the professional participant’s confidentiality. Permission should, therefore, be sought from the relevant institution or authority to seek and release information. Professional body guidelines on this matter should be consulted where relevant.

3.3.3.2 Patients

A patient may be defined as an individual who:

“has sought or accepted medical care” or

“has been selected from the general population because of known or suspected abnormality”.

[Royal College of Physicians, 1990]

There are further matters to consider with regard to patients as participants, e.g.:

- a patient’s ability to consider the implications may be impaired;
- patients are dependent on health practitioners – a sense of obligation might, therefore, be present, and such a conflict of interest may need to be considered when formulating the proposal.

3.3.3.3 Special groups

The third basic ethical principle relates to justice, which refers to the ethical obligation to treat each person in accordance with what is morally right and proper, and to give each person what is due to him or her. The concept of justice in this regard is universally applicable to all research participants. However,
special groups may, and in some instances must, require further attention. The competence of individuals within these special groups to assess risk, and therefore to give informed consent, is the main issue here.

“In the ethics of research involving human subjects the principle refers primarily to distributive justice, which requires the equitable distribution of both the burdens and benefits of participation in research. Differences in distribution of benefits and burdens are justifiable only if they are based on morally relevant distinctions between persons; one such distinction is vulnerability. "Vulnerability" refers to a substantial incapacity to protect one's own interests owing to such impediments as lack of capability to give informed consent, lack of alternative means of obtaining medical care or other expensive necessities, or being a junior or subordinate member of a hierarchical group. Accordingly, special provisions must be made for the protection of the rights and welfare of vulnerable persons.”

[Council for International Organizations of Medical Sciences (CIOMS), 2002]

Researchers should ensure that competence is socially constructed and determined by the context and process of research rather than being a fixed property of participants. This is true regardless of what type of participants may be involved.

The following groups may be identified:

(a). Children (both under 16 and in the 16-18 category)

‘Gillick competent’ children (i.e., those children who, although under 16, are deemed to have sufficient understanding to give consent in their own right) should be selected before younger children.

Competence involves:

- The ability to understand information;
- The belief that the information applies to oneself;
- The ability to retain, ask questions about and reflect upon the information long enough to make a decision.

Before undertaking research involving children, the investigator must ensure that:

- the research might not equally well be carried out with adults;
- the purpose of the research is to obtain knowledge relevant to the health needs of children;
- a parent or legal representative of each child has given permission;
- the agreement (assent) of each child has been obtained to the extent of the child’s capabilities;
- a child’s refusal to participate or continue in the research must always be respected.

[CIOMS 2002]

(b). Persons with Mental Health or Behavioural Disorders

Research on individuals are not capable of giving adequately informed consent is governed by the provisions of the Mental Capacity Act 2005. Researchers wishing to conduct research involving such individuals must ensure they comply with the Code of Practice, which can be found at http://www.justice.gov.uk/guidance/mca-code-of-practice.htm.

(c). Older People

Particular care should be taken if the person is living in long-stay accommodation, in hospital or in a residential home.

(d). Persons with Learning Difficulties

(e). Pregnant Women (including during the postpartum period)

(f). Others

Other vulnerable groups might include people to whom the researcher owed a duty of care, where there is a real or potential conflict of interest, or possibly, where subjects might feel that receipt of services may be dependent on participation in the study (e.g., asylum seekers, refugees, employees, students).

3.3.4 Risks

Before becoming involved in any research endeavour, potential risks need demonstrably to be weighed against the benefits, i.e., a risk/benefit analysis needs to be conducted. Normally, for the purposes of undertaking a project/dissertation/thesis within the department, you should not consider any design which goes beyond a minimal risk. Essentially, minimal risks are those which can be ignored, i.e., the risk itself is trivial and/or the chance of it arising is remote.

3.3.5 Deception

As a general rule, people should know beforehand that they are participating in a study and being asked to give their consent. Some studies may include an aspect about which the participant is not fully informed (for example, a placebo treatment may be used, in which case informing the participant would invalidate the research). This procedure must first be deemed acceptable by a Research Ethics Committee before being applied, and you will need to be able to justify its use to the Committee.

It is recognised that there is a long history of covert sociological research, and in many cases it is necessary to operate covertly. Nevertheless, the researcher must be prepared to convince an ethics committee of the necessity of conducting such research without the knowledge or consent of the participants.
In health care research, there are also concerns regarding withholding of treatment in order to maintain a control group. Opinion has grown increasingly against this practice, and it is suggested that you consider another type of design. Otherwise, the justification for the use of a control group must be highlighted and justified in the research proposal.

### 3.3.6 Notification of study participation

If a study originates in a hospital or other health institution, the participant’s GP and Consultant should be informed of the study. This usually takes the form of an explanatory letter with the request that if the GP has any concerns, you should be contacted regarding them by a certain date. In some cases the Consultant may be the more appropriate person to contact.

### 3.3.7 Requirements of professional bodies

Even if ethical clearance is obtained from the relevant bodies outlined above, the researcher is not necessarily absolved from a duty of care. The general and continuing duty of care may also be subject to guidelines and rules of conduct laid down in the Codes of Practice/Ethics established by professional and/or statutory bodies. Care should be taken to consult the relevant documents, in addition to the general guidelines given above.

## 4 References

Association of Social Anthropologists: [www.theasa.org/ethics.htm](http://www.theasa.org/ethics.htm)

British Association of Social Workers: [www.basw.co.uk/](http://www.basw.co.uk/)


The British Sociological Association: [www.britsoc.co.uk/equality/](http://www.britsoc.co.uk/equality/)

Declaration of Helsinki: [www.wma.net/e/policy/b3.htm](http://www.wma.net/e/policy/b3.htm)

Economic & Social Research Council: [www.esrcsocietytoday.ac.uk/ESRCInfoCentre/index.aspx](http://www.esrcsocietytoday.ac.uk/ESRCInfoCentre/index.aspx)

Health Professions Council: [www.hpc-uk.org/aboutregistration/standards/](http://www.hpc-uk.org/aboutregistration/standards/)

Medical Research Council: [www.mrc.ac.uk/PolicyGuidance/EthicsAndGovernance/index.htm](http://www.mrc.ac.uk/PolicyGuidance/EthicsAndGovernance/index.htm)


Royal Academy of Engineering: [www.raeng.org.uk/policy/ethics/default.htm](http://www.raeng.org.uk/policy/ethics/default.htm)

The Social Research Association: [www.the-sra.org.uk/ethical.htm](http://www.the-sra.org.uk/ethical.htm)
5 Appendix A: Short texts

Anonymity and Confidentiality

It is common, in research ethics applications for approval, for the proposer to display a lack of understanding of these terms and/or to demonstrate confusion between the two, or even to treat them as being the same. Another common error is to fail to provide sufficient detail in relation to either or both when applied to the particular study in question. For guidance, the proposer may wish to note the following:

Confidentiality

Confidentiality arises from both the ethical and legal concept of respect for the person – in this instance, respect for information entrusted (perhaps in an assumed relationship involving secrecy) about an individual by one person to another, i.e., the research participant to the researcher. The element of trust, embedded in both ethics and law, assumes known boundaries for the communication of private information and safeguards to assure that these boundaries are not exceeded, except in certain public interest circumstances, for example, child protection. Thus, the researcher has a duty to make explicit what the boundaries of trust will be in the relationship and, where relevant, where the public interest in disclosure is likely to override the duty of confidentiality. Moreover, the researcher needs to satisfy the research ethics reviewers as to precisely how security of data is to be assured, particularly in relation to the requirements of the Data Protection Act 1998.

Anonymity

On the other hand, anonymity concerns information which does not identify an individual directly, and which cannot reasonably be used to determine identity. Thus, anonymisation will require the researcher to remove the name, address, and any other detail, or combination of details, that might support identification.

Pseudonymity

Pseudonymised information should also be noted (Department of Health 2003). It is similar to anonymised information in that, in the possession of the holder, it cannot reasonably be used by the holder to identify an individual. However, it differs in that the original provider of the information may retain a means of identifying individuals. This will often be achieved by attaching codes, or other unique references to information, so that the data will only be identifiable to those who have access to the key or index. Pseudonymisation allows information about the same individual to be linked in a way that true anonymisation does not.
**Consent in research ethics**

**The Ethical and Legal Basis**

The ethical basis for consent is **autonomy**, which refers to the obligation on the part of the investigator to respect each participant as a person capable of making an informed decision regarding participation in the research study. This obligation translates, in a legal context, into 'ownership' of one's person; a failure to honour this obligation being known as trespass to the person, or assault. Moreover, there is now a legal requirement under the Mental Capacity Act 2005 for **capacity**, and thus autonomy, to be assumed, unless and until the contrary is demonstrated. The principle of autonomy normally finds expression in the Consent Form, accompanied by the Research Participant Information Sheet.

Definitions of informed consent are wide-ranging, but, in essence, the default position in terms of research ethics is that *a person gives valid informed consent to take part in a study only if that person's decision:*

- is given freely after that person is informed of the nature, significance, implications and risks of the study; and
- either:
  - is evidenced in writing, dated and signed, or otherwise marked, by that person so as to indicate his consent, or
  - if the person is unable to sign or to mark a document so as to indicate his consent, is given orally in the presence of at least one witness and recorded in writing.

There are, of course, a number of exceptions to this – most notably, in situations involving mental incapacity, where the provisions of the Mental Capacity Act with regard to personal consultees become engaged (see separate Study Guide); and in relation to questionnaires, where, in most cases, the principle of **implied consent** may be invoked – i.e., where, usually in an anonymous context, consent is apparent by the return of a completed document.

The component elements and requirements of informed consent might usefully be stated as follows:

**Disclosure:** The potential participant must be informed as fully as possible of the nature and purpose of the research, the procedures to be used, the expected benefits to the participant and/or society, the potential of reasonably foreseeable risks, stresses, and discomforts, and alternatives to participating in the research. There should also be a statement that describes procedures in place to ensure the confidentiality and/or anonymity of the participant. The document should make it clear whom to contact with questions about the research study, research subjects’ rights (where relevant), and in case of injury.

**Understanding:** The participant must understand what has been explained and must be given the opportunity to ask questions and have them answered by one of the investigators. The informed consent document must be written in lay language, avoiding any technical jargon.

**Voluntariness:** The participant’s consent to participate in the research must be voluntary, free of any coercion or promises of benefits unlikely to result from participation. Moreover, care needs to be taken that “freely given” in the context of a potential conflict of interest is rigorously safeguarded.
**Competence:** The participant must be competent to give consent – i.e., capable of understanding and retaining the information, and capable of weighing risks and making a choice. If the participant is not competent due to mental status, disease, or emergency, the principles of the MCA 2005 become engaged.

**Consent:** The potential human participant must authorize his/her participation in the research study, preferably in writing, although at times an oral consent or assent may be more appropriate.

**Consent in relation to human tissue**

Where a researcher wishes to use human tissue in a research project, there are additional provisions which are required for compliance with the Human Tissue Act (HT Act), and are set out by the Human Tissue Authority (HTA).

**General provisions**

Consent under the HT Act relates to the purpose(s) for which material might be stored or used. As research is a scheduled purpose under the HT Act, the requirements of the HT Act apply. For consent to be valid it must be given voluntarily by an appropriately informed person (who could be a child) who has the capacity to agree to the activity in question.

Consent can be general, that is, it is possible to ask for consent to store and use tissue for an unspecified number of research projects. If there is any possibility that a researcher may wish to use tissue originally obtained for one project in another project, then that possibility should be included on the original consent form. If consent is withdrawn after the sample(s) has been used for research, it is not necessary to withdraw the data related to that sample from the project.

If material is obtained from a UK-based source, then the researcher must ensure that consent was properly obtained. Proof of consent should be supplied with the material, and retained centrally within the College/Research Institute.

Tissue which has been obtained from a non-UK source does not require consent. However, it is good practice to see if there is any information available from the source which indicates that consent has been obtained in an appropriate manner.

**Consent from children and persons lacking capacity**

Under the HT Act, a child is defined as a person under the age of 18. IF a child is considered to be competent to give valid consent, then the consent for removal, storage and/or use of the tissue should be given by the child. It is important to make sure the child has consented voluntarily and has not been unduly influenced by anyone else. For removal, storage and use of tissue from persons lacking capacity to consent (for the purpose of research), the researcher must refer to sections 30 – 34 of the Mental Capacity Act 2005.

**Use of tissue from deceased persons**

Consent is required for the removal, storage and use of tissue from a deceased person for any schedule purpose. The University’s license from the HTA covers research, and education or training relating to human health. Consent must be obtained for either of those purposes. If a person has given consent for the use of tissue to take place after their death, then that consent is considered sufficient. If consent was not obtained prior to the person's death, then it must be obtained from a nominated representative or a person in a “qualifying relationship”.

Detailed information regarding how to obtain consent for remove, storage and/or use of tissue from a deceased person is available from the HTA’s Code of Practice.
1 (Consent)
(http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code1consent.cfm).

**Use of tissue from living persons**

Consent from the living is required if the tissue is to be stored and used for specifically for **research purposes**. Consent is **not** required if the tissue is being stored and used for education or training relating to human health. **Foetal tissue** is regarded as the mother’s tissue.

The HTA’s Code of Practice 1 (Consent), referenced above, includes several useful charts in the appendices as a guide to consent requirements.

It should be noted that the University Research Ethics Committee is **not** a “recognised research ethics committee” as referenced in the HT Act or any HTA document.
Consent related to human tissue

(Extracted from the Code of Practice on Consent issued by the Human Tissue Authority)

Table setting out the consent requirements under the HT Act for scheduled purposes

<table>
<thead>
<tr>
<th>Scheduled purpose</th>
<th>Consent required for human tissue from the living</th>
<th>Consent required for human tissue from the deceased</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Removal</td>
<td>Storage</td>
</tr>
<tr>
<td>Anatomical examination</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Determining the cause of death **</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Establishing after a person’s death the efficacy of any drug or other treatment administered to them</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person)</td>
<td>X*</td>
<td>✓</td>
</tr>
<tr>
<td>Public display</td>
<td>X*</td>
<td>✓</td>
</tr>
<tr>
<td>Research in connection with disorders, or the functioning, of the human body</td>
<td>X*</td>
<td>✓</td>
</tr>
<tr>
<td>Transplantation</td>
<td>X*</td>
<td>✓</td>
</tr>
<tr>
<td>Clinical audit</td>
<td>X*</td>
<td>X</td>
</tr>
<tr>
<td>Education or training</td>
<td>X*</td>
<td>X</td>
</tr>
<tr>
<td>Performance assessment</td>
<td>X*</td>
<td>X</td>
</tr>
<tr>
<td>Public health monitoring</td>
<td>X*</td>
<td>X</td>
</tr>
<tr>
<td>Quality assurance</td>
<td>X*</td>
<td>X</td>
</tr>
</tbody>
</table>

✓ Consent is required under the HT Act
X Consent is not required under the HT Act
* Consent is required under the common law for removal of tissue from the living
** Consent is not needed for investigating the cause of death under the authority of the coroner
Table setting out when consent is required for different activities and when it is recommended as good practice

<table>
<thead>
<tr>
<th>Activity (consent may be sought for more than one activity at the same time)</th>
<th>Consent required</th>
<th>Consent recommended as good practice</th>
<th>Guidance</th>
</tr>
</thead>
</table>
| Storage and/or use of tissue from the living for the scheduled purposes of:  
I. Obtaining scientific or medical information which may be relevant to any other person, now or in the future  
II. Public display  
III. Research  
IV. Transplantation | ✔ | | Paragraph 113 |
| Storage and/or use of tissue from the living for research, where the research is ethically approved and the tissue is non-identifiable | X | ✔ | Paragraphs 117 – 123 |
| Storage and/or use of tissue from the living for the scheduled purposes of:  
I. Clinical audit  
II. Education or training relating to human health  
III. Performance assessment  
IV. Public health monitoring  
V. Quality assurance | X | | Paragraph 114 |
| Diagnosis and treatment | X | Consent is required under the common law for removal of tissue from the living | Paragraphs 115 – 116 | • Department of Health guidance [www.dh.gov.uk/consent](http://www.dh.gov.uk/consent)  
• Northern Ireland Reference guide to consent for examination, treatment or care [www.dhsspsni.gov.uk/consent-referencguide.pdf](http://www.dhsspsni.gov.uk/consent-referencguide.pdf)  
• Welsh Assembly Government Reference guide to consent for examination or treatment [www.wales.nhs.uk/consent](http://www.wales.nhs.uk/consent) |
## Table setting out when consent is required for different activities and when it is recommended as good practice

<table>
<thead>
<tr>
<th>Activity</th>
<th>Consent required</th>
<th>Consent recommended as good practice</th>
<th>Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Removal, storage and/or use of material from the deceased for any scheduled purpose</td>
<td>✔</td>
<td></td>
<td>Paragraph 72</td>
</tr>
<tr>
<td>Criminal justice</td>
<td>X</td>
<td>Paragraph 112</td>
<td>• Section 39 of the HT Act (Criminal justice purposes) <a href="http://www.legislation.gov.uk/ukpga/2004/30/section/39">www.legislation.gov.uk/ukpga/2004/30/section/39</a></td>
</tr>
<tr>
<td>Storage and/or use of imported material</td>
<td>X</td>
<td>✔</td>
<td>Paragraph 69</td>
</tr>
<tr>
<td>DNA analysis (other than for an excepted purpose)</td>
<td>✔</td>
<td></td>
<td>Paragraphs 152 – 156</td>
</tr>
<tr>
<td>DNA analysis (for an excepted purpose)</td>
<td>X</td>
<td></td>
<td>Paragraphs 154 – 156</td>
</tr>
<tr>
<td>Making and displaying of images</td>
<td>X</td>
<td>✔</td>
<td>Paragraphs 70 – 71</td>
</tr>
<tr>
<td>Storage and/or use of existing holdings</td>
<td>X</td>
<td></td>
<td>Paragraphs 65 - 68</td>
</tr>
</tbody>
</table>
Criminal Records Bureau – CRB checks for researchers

The CRB’s aim is to help organisations in the public, private and voluntary sectors by identifying people who may be unsuitable to work with children or other vulnerable members of society.

The Criminal Records Bureau (CRB) discloses information regarding previous convictions, etc. to employers to protect children and vulnerable adults. If you are researching such groups, it is now good practice to have gone through this clearance. There are three levels of disclosure: ‘basic’, ‘standard’ and ‘enhanced’. Enhanced disclosure is the level most appropriate for research with children and vulnerable adults.

Research staff and students working on research projects which bring them into contact with children or vulnerable adults, alone or unsupervised, for a significant period of time will require a CRB check. The CRB check would either be applied on the recruitment of staff, where it is known and planned, or at the start of field work when it emerges during a project. The process can take several weeks, so it is recommended that the need for CRB checks is considered as early as possible in the development of a research programme.

Two different systems are in place in the University:

- Staff should apply for a CRB check via the HR manager allocated to the College where the member of staff is employed. Anyone who is paid via payroll should approach HR for a CRB application form; this includes researchers who have a one year fixed term contract and are paid through the payroll system. Staff who are also PhD students and who are paid via payroll should also apply via the HR route.

- Students (undergraduate and post graduate including PhD, self-funding, funded and bursary funded) should apply to Registry for an application form. Usually the College would pay for the CRB check under these circumstances.

Further information about the processes within the University can be found at the following links:

http://www.brunel.ac.uk/__data/assets/pdf_file/0017/133226/August2014UpdatedSafeguardingPolicy.pdf

(provides further information about whether you need a CRB check)

Further information about the Criminal Records Bureau can be found at:

https://www.gov.uk/government/organisations/disclosure-and-barring-service

Research Ethics Committees Requirements

The Research Ethics Committee will usually require confirmation that a CRB check has been obtained where researchers are working with participants who are under 16/18 or fall into the category of vulnerable adults. Evidence of the check should be presented along with all other documentation when making an application to the REC. It is the responsibility of the applicant to provide this confirmation.
**Does my research project need ethical review?**

Any research which uses human participants must receive ethical review and approval before the work can start. Conducting such research without ethical approval is a violation of University policy.

**When am I using “human participants”?**

If your research involves collecting data from people, then you are using human participants. Collecting data can range from taking blood, to physical tests, to interviews, observation, or even just answering questionnaires.

Even if the data will be anonymised when the results are reported, you still need to have ethical approval.

**What if my questionnaire is just a service review?**

If your questionnaire is not being used as part of a research project, then you probably don’t have to have ethical approval. It depends on what you intend to do with the results.

For instance, course evaluations, internal service satisfaction surveys and the like, where there is no intention to publish the results beyond the University, would not need ethical approval.

On the other hand, if a student decides to conduct such a survey as part of his or her coursework, then that should have ethical approval.

**What does ethical approval cover?**

In applying for ethical approval, you will need to prove that you have considered the following:

- Consent
- Information for the participants
- Any physical or mental risks to the participants, and the mitigation of those risks
- Any risks to you or other researchers on the project, and their mitigation

**What is the process for gaining ethical approval?**

To receive ethical approval, your proposal must be reviewed by a Research Ethics Committee (REC) (we will assume for now that you won’t be using NHS staff, patients or facilities).

Each College has its own REC. You or your supervisor should check with the College Research Ethics Officer to determine what procedures need to be followed in sending your proposal to the REC.

Any College REC may, if it wishes, send an application to the UREC for consideration.

You will probably start by filling out a Research Ethics Review Checklist. Depending on the answers you provide, you may then have to fill out a full Application Form for Research Ethics Approval.
You can refer to the accompanying flowchart for a pictorial representation of the process.

**What happens after I receive ethical approval?**

Once you have received ethical approval from the appropriate REC, you can start recruiting your participants and begin the work. On any information that is provided to the participants, you must include a statement which indicates that you have received ethical approval for the project.

**What if I don’t bother to get ethical approval?**

If you are using human participants in your research, and go ahead with the project without receiving ethical approval, you will be subject to disciplinary proceedings. Also, the University’s insurer will not cover you for professional or clinical liability.
Completing IRAS form
Following your College approval procedures
Carrying out research

[Not working with people or their data]
[Work involves people or their data]
[Only involves anonymised data]
[Work involves NHS]

Completing IRAS form
Following your College approval procedures
Carrying out research

Route to ethically approved research

[All research completed]
Insurance matters and research

The University holds comprehensive insurance for professional liability and for professional negligence with respect to procedures up to and including clinical trials.

The professional liability insurance covers all Brunel University students and staff engaged in research. It also covers all members, whether internal or external, of any Research Ethic Committee with respect to decisions made by those committees.

Of course, if the student or member of staff purposely commits or condones a dishonest or fraudulent act or omission, they are not covered.

- The location in which research is conducted is of no consequence to the University's insurers.
- All members of Research Ethics Committees, whether those members are internal or external, are covered by the University's insurance policy with respect to the decisions made by the Committee.
- If there is any doubt as to whether a particular aspect of a research proposal is covered by the University's policies, the issue should be referred to the Insurance Co-ordinator. This might include cases where the research itself is risky, for either the researcher or the participants, or where it might be taking place in a country or region which is on the Foreign Office's list of places to which travel is not advised.
- You may e-mail questions about insurance coverage to res-ethics@brunel.ac.uk.
- University researchers are covered for any claim made against them in the UK. They are not covered if a claim is made to a court in the United States or Canada; however, it is considered unlikely that a suit would be initiated there, as the University has no assets in those countries.
- If a researcher who is not a member of Brunel staff is conducting research here, but is not the principle investigator (PI), then Brunel’s insurance covers that researcher while they are onsite. If that researcher is the PI, then he/she is covered by their institution's insurance.
- If a researcher, whether member of staff or a student, fails to obtain ethical approval when that is required, and something untoward occurs which results in harm to a participant in the research, the University will not indemnify the researcher.
- If a device is being used in a research project, liability insurance will be provided by the manufacturer as long as the device is being used in a manner deemed to be appropriate. The University is unlikely to provide coverage if a device is to be used in a way not envisaged by the manufacturer.
**Intellectual Property Rights**

Any research project is likely to involve intellectual property (IP). IP involves one or more of the following:

- Copyright
- Moral rights
- Patents
- Know-how
- Design rights
- Trademarks

In general, the originator of any copyright material or any patentable invention owns the IP for that material or object. Students at the University retain the IP rights for any work they do during the course of their studies, unless a written agreement has been signed which states otherwise.

The opposite is true for members of staff. Unless otherwise specified, the University owns the IP for any copyright or patentable work produced by an employee.

A brief examination of each of the bullet points above follows:

**Copyright**

Copyright protection is automatic – it exists as soon as a copyright work is created. The following are examples of works that attract copyright protection:

- Original literary works – for example novels, newspaper articles and song lyrics
- Work in electronic form such as web pages, databases and computer software
- Original artistic works – for example drawings, paintings, photographs, engravings, sculptures and works of artistic craftsmanship
- Original dramatic works – for example works of dance or mime
- Original musical works
- Sound recordings in any form
- Films
- Broadcasts

Published results of research are copyright works. The University waives its rights to ownership of these, but retains the right to use, modify or copy them for teaching and research purposes.

**Moral rights**

This concept could also be known as “credit where credit is due”. If you reference another person’s work, either in writing or in a presentation, you are morally and ethically obliged to acknowledge that person’s contribution. The work in question may or may not be written; it may be an idea, a creative work, or even assistance in the laboratory.
**Patents**

A patent is used to protect an invention, and prevents anyone other than the patent holder from making, using or selling the invention without the express permission of the patent holder. A patent is only valid in the country in which it was registered.

The University owns the rights to a patentable invention or process which has been developed by a member of staff in the course of their employment. Should the invention or process be successfully commercialised, then the University will share the proceeds with the member of staff.

**Know-how**

Know-how consists of such things as unpatented inventions, designs, drawing, and procedures and methods which, along with the professional skills and experience of a company's personnel, could provide another company with a competitive advantage in manufacturing or using a product.

The protection given to know-how is usually the same as that provided for trade secrets.

**Design rights**

“Design” refers to the features of either a whole product, or part of a product. It includes such things as the shape, decoration, texture or materials used.

The rights available can refer to either two-dimensional or three-dimensional designs. Copyright and Registered Design rights protect rights for both two- and three-dimensional designs; Unregistered Design rights relate to three-dimensional designs.

**Trademarks**

A trademark is any sign that distinguishes the goods or services offered by a company from those offered by any other company. The Bass Brewery logo was Britain's first registered trademark.

A trademark does not have to be a logo; it can be words, colours, slogans, pictures, three-dimensional shapes, sounds, gestures or smells or any combination of these.

Trademarks can be either registered or unregistered; the first person (natural or legal) to register a trademark owns it.

For more information, refer to the intranet pages for the Research Support and Development Office (RSDO): [https://intra.brunel.ac.uk/s/rsdo/Pages/default.aspx](https://intra.brunel.ac.uk/s/rsdo/Pages/default.aspx).

The University has a policy on intellectual property, which can be found here: [http://www.brunel.ac.uk/about/administration/policies-and-other-important-documents](http://www.brunel.ac.uk/about/administration/policies-and-other-important-documents).
Research involving adults unable to consent for themselves and children

Adults unable to consent for themselves

The Mental Capacity Act (2005) has a bearing on research involving a person who lacks capacity to consent. Research covered by the Act cannot include people who lack capacity to consent unless it is approved by an ‘appropriate body.’ As it stands, that body is an NHS research ethics committee, flagged to review research which may involve participants who lack capacity to consent, whether or not this research takes place under the auspices of the NHS.

The Committee can only approve research if the study is linked to:

- an impairing condition that affects the person who lacks capacity, or
- the treatment of that condition

and

- there are reasonable grounds for believing that the research would be less effective if only people with capacity are involved,

and

- the researcher has made arrangements to consult carers and to follow the other requirements of the Act.

Research must also meet one of two requirements:

1. The research must have some chance of benefiting the person who lacks capacity. The benefit must be in proportion to any burden caused by taking part,

or

2. The aim of the research must be to provide knowledge about the cause of, or treatment or care of people with, the same impairing condition, or a similar condition.

The National Research Ethics Service (NRES) has developed guidance material to help researchers navigate this potentially complex area. Follow the link http://www.nres.npsa.nhs.uk/ to ‘research involving adults unable to consent for themselves’. This link will lead to the following and other relevant publications which can be accessed either directly or via an external link from the NRES site:

- NRES guidance on research involving adults who lack capacity to consent for themselves (incorporating guidance on the Mental Capacity Act, 2005)
- Guidance for nominating a consultee for research involving adults who lack capacity to consent
- The Mental Capacity Act 2005

The Mental Capacity Act Code of Practice (2007) http://www.dca.gov.uk/legal-policy/mental-capacity/mca-cp.pdf can be accessed on line, in full, from this link. Chapter 11 provides guidance about the how the Act affects research projects involving a person who lacks capacity and details the responsibilities of the researcher (see below). Chapter 4 outlines how capacity is assessed and chapter
3 outlines the steps that should be taken to help people make a decision for themselves.

Briefly, the responsibilities of the researcher in studies where participants lack capacity to consent are:

- Researchers should assume that a person has capacity to make a decision unless it can be established that they lack capacity, a person's capacity must be assessed specifically in terms of their capacity to make a particular decision at the time it needs to be made (see chapter 4 of the MCA Code of Practice)

- The potential participant must receive support to try to help them make their own decision (see chapter 3 of the MCA Code of Practice)

- Researchers must obtain approval from the ‘appropriate body’ (NRES)

- The views of any carers and other relevant people must be sought before involving a person who lacks capacity in research. This means acting in accordance with section 32 of the MCA to determine whether the person should be included in the act. (See NRES guidance above)

- The wishes, objections and feelings of the person must be respected

- More importance should be placed on the person’s interests than on those of science and society

- Even when a consultee agrees that a person can take part in research the researcher must still consider the person’s wishes and feelings

- Researchers must not do anything the person who lacks capacity objects to. They must not do anything to go against any advanced decision to refuse treatment or other statement the person has previously made expressing preferences about their care or treatment. Researchers must assume that the person's interests in this matter are more important than those of science and society.

A researcher must withdraw someone from a project if:

- they indicate in any way that they want to be withdrawn (e.g., if they become upset or distressed), or

- if any of the Act's requirements are no longer met


Researchers who plan to conduct research with people who lack capacity to consent must complete the NRES Integrated Research Application System form available from: [https://www.myresearchproject.org.uk/](https://www.myresearchproject.org.uk/)

**Research Involving Children and Young People**

(From Principles to Guide Research Involving Children (Hull, 2000, MRC, 2004))

Research involving children is important for the benefit of all children and should be supported, encouraged and conducted in an ethical manner.
Children are not small adults; they have an additional unique set of interests. Research should only be done on children if comparable research in adults could not answer the same question.

The purpose of the research must be to obtain knowledge relevant to the health, well-being or healthcare needs of children (for research in health but the principles apply to other fields).

Researchers can only involve competent children if they have obtained their informed consent beforehand.

A child's refusal to participate or continue in research should always be respected.

If a child becomes upset by a procedure, researchers must accept this as a valid refusal.

Researchers should involve parents/guardians in the decision to participate wherever possible, and in all cases where the child is not yet competent.

Researchers should attempt to avoid any pressures that might lead the child to volunteer for research or that might lead parents to volunteer their children, in the expectation of direct benefit (whether therapeutic or financial).

Research involves partnership with the child and/or family, who should be kept informed and consent to separate stages of the project. Obtaining consent is a continuing process, rather than a one-off occurrence. Children and their families are likely to appreciate some recognition of their role in this partnership, such as a certificate of participation.

Researchers must take account of the cumulative medical, emotional, social and psychological consequences of the child being involved in research.

**Competence and Consent**

Research with children and young people who lack capacity under the MCA is not covered in the Mental Capacity Act Code of Practice, although guidance is planned for future publications.

UK law is untested with regard to the legal age to consent to take part in research. It is possible to apply the principle of Gillick competence for research in the UK. This can be summarised as children who are felt to be competent to understand the research proposal and make decisions about it can give consent on their own behalf. It is unwise to use this principle for children less than ten years of age. It would be unwise to include a child in a research project where the child agrees but the parents do not, notwithstanding the Gillick judgement. It should be noted that the threshold for understanding will vary according to the complexity of the research (NRES guidance documents and RCP, 2007).

Sufficient information should be provided in an age-appropriate format. NRES guidance documents suggest different information sheets and verbal explanations should be provided for children or young people aged 11-15 years, children aged 6-10 years and young children aged 5 years and under. Separate, adult versions, should be provided for parents or guardians. Even when it is anticipated that a parent will consent for a child, the child should still be given information about the study in an appropriate format. (NRES, 2007)
Risk and research involving children

(From the Royal College of Paediatric and Child Health (UK) (http://www.rcpch.ac.uk/))

When considering harm, rather than the lack of possible benefit, it starts with a broad, cautious statement, ‘childhood is a vulnerable formative time, when harms can have serious impact. Potential harms should be assessed carefully before children are put at risk.’ Overall, it adopts a utilitarian stance and recognises that some ethical research may subject children to some harm. ‘The attempt to protect children absolutely from the potential harms of research denies any of them the potential benefit.’ Risk will need to be carefully considered and any harm will need to be justified within a proposal, however minimal.

Although there is a lot of information available on the web, two particularly useful resources are the Barnardo’s document of ethical research practice, (http://www.barnardos.org.uk/resources) and the National Youth Agency’s ethical framework document (http://www.nya.org.uk). Follow the links to research, research ethics, and ethical framework document. These organisations provide useful information about all aspects of the research process including the participation and consent procedures for hard to reach groups, consent as a continuing process rather than a one off decision, the importance of proving support from external agencies, debriefing following research procedures, etc.

References


Negligent/Non-Negligent Harm

The issue of Sponsorship – i.e., the duties and responsibilities of the host institution (in this case, Brunel University) – often involves consideration of what insurance and indemnity arrangements are in place to cover “things going wrong”. No matter how cautious and diligent the University Research Ethics Committee (and the College RECs acting under delegated powers) has been in conducting an assessment of risk at the review stage prior to approval, and even with adequate supervision and monitoring, the conduct of the study might suffer compromise through misconduct. Some examples might be:

- Failure to obtain consent (where this was a prerequisite for ethics approval). This, in some cases, becomes battery, based on the notion of trespass to the person. Where such conduct involves intent within the meaning of the criminal law, then the default position of vicarious liability (where an employer/sponsor is held legally liable for the wrongful actions of employees if committed in the course of their employment) is contradicted by the crossover from non-criminal to criminal responsibility. Normally, the liability will then become a matter of personal responsibility.

- Breach of confidence: an action for damages could lie here, but the Data Protection Act 1998 might also be engaged in relation to personal liability in the criminal law.

Negligent Harm: any action or process that is held by a court to have caused harm as a result of lack of care, omission of duty or an act of carelessness towards the participant in a research project.

This is the legal liability that arises where a participant is harmed in the course of research, and an individual or group of individuals can be demonstrated to have caused that harm because of their negligence through, for example, not following an agreed procedure according to set policy or protocol. In such cases, the University is liable or vicariously liable and would be responsible for dealing with claims arising against the University for the harm caused.

As indicated above, there are, however, exceptions to the vicarious liability principle. The University will only extend indemnity cover to its staff (both substantive and honorary) and students conducting research projects involving human participants if those projects have been approved by the University Research Ethics Committee. Similarly, substantive, unauthorised departures from the approved protocol will position researchers “on a frolic of their own”.

Non-Negligent Harm: circumstances where there is no specifically identified causative factor relating to the harm of a participant in a research project, but harm is likely, on the balance of probabilities, to have arisen from the participant taking part in the research.

Non-negligent harm arises where an individual has been harmed in the course of research, through no fault of the individual or institution involved in the research, and even though the correct policies and procedures have been followed. The University has the responsibility (where appropriate) for providing financial cover for damages or compensation arising from non-negligent harm.
**Scientific Fraud and Bad Research Practice**

**What is it?**

Scientific fraud occurs when proposing, performing, reviewing research and when reporting results. The most commonly discussed instances involve the following;

**Falsification** – altering truthful information, e.g., selective submission of data, consent forms, images to exclude or manipulate inconvenient data

**Fabrication** – inventing information where none previously existed, e.g., generating bogus data, fictitious information sheets or consent forms

**Plagiarism** – the unauthorized use, misappropriation or close imitation of the language and writings (literary theft), ideas, inventions, intellectual property of another and passing them off as one’s own original work, i.e., without acknowledgment or permission

Fraud, in that it always contains intent, is by definition misconduct and once suspected should be fully reported and investigated.

Other forms of research misconduct may also occur through the violation of other ethical standards of the scientific community, for example, deliberate and dangerous or negligent deviations from accepted practice and standards. It includes failure to follow an agreed protocol if this failure results in unreasonable risk or harm to humans or other vertebrates or the environment, and facilitating misconduct in research through collusion, or concealment of such actions by others.

The Research Councils UK (RCUK) defines such activities within a **breach of the duty of care** as follows:

This may involve deliberately, recklessly or by gross negligence:

- Disclosing improperly the identity of individuals or groups involved in research without their consent or other breach of confidentiality

- Placing any of those involved in research in danger, whether as subjects, participants or associated individuals, including reputational danger where that can be anticipated, without their prior consent, and without appropriate safeguards even with consent

- Not taking all reasonable care to ensure that the risks and dangers, the broad objectives, and the sponsors of the research, are known to participants or their legal representatives to ensure appropriate informed consent, and that this is obtained explicitly and transparently

- Not observing legal and reasonable ethical requirements or obligations of care for animal subjects of research

- Not observing legal and reasonable requirements or obligations of care for the protection of the environment

- Improper conduct in peer review of applications or publications, including gross misrepresentation of the content of material, inadequate disclosure of clearly limited competence, or abuse of material provided in confidence for peer review.
Management and preservation of data and primary materials

This may include failing to ensure that relevant primary data and research evidence are preserved and accessible to others for reasonable periods after the completion of the research. This is a shared responsibility between researcher and the research organisation, but individual researchers should always ensure that primary material is available to be checked. Such conditions should also be applied where ownership of data may rest with third parties, for example, where there is commercial sponsorship of research.

Furthermore, any plan or conspiracy or attempt to do any of the above is also considered as researcher misconduct.

Examples

Claxton (2005) documents and compares many of the better-known cases of scientific fraud, including that of Jan Hendrik Schön, a researcher and prolific author in the field of nanotechnology. Over a period of four years (1998-2002) he published over 90 papers, including 15 papers in *Science* and *Nature*. A problem emerged in that, despite spending millions of dollars his results could not be replicated or independently verified. One of Schön’s colleagues raised concerns to a University colleague, who examined the publications and alerted the journals to inconsistencies in the data. A review committee concluded that Schön had duplicated, falsified and destroyed data. He was dismissed from the laboratory and although admitting mistakes he continued to defend his work (see Claxton 2005, for details).

Martinson et al (2005) published the top ten fraudulent and other questionable research practice behaviours admitted by US scientists. Examples include the following;

1. Falsifying or cooking research data
2. Ignoring major aspects of human-subject requirements
3. Not fully disclosing involvement in companies whose products are based on the researcher’s work
4. Relationships with students, participants or clients that may be interpreted as questionable
5. Failing to present data that contradict one’s own previous research
6. Overlooking others’ use of flawed data or questionable interpretation of data
7. Changing the design, methodology or results of a study in response to pressure from a funding source
8. Publishing the same data or results in two or more publications (redundant publication)
9. Inappropriately assigning authorship credit (gift authorship)
10. Cutting corners in a hurry to complete a project (de Vries et al, 2006)
11. Using funds from one project to get work done on another project (de Vries et al, 2006)
12. Providing an overly positive or negative recommendation (de Vries et al, 2006)

13. Dropping observations or data points from analyses based on a gut feeling that they were inaccurate

14. Inadequate record keeping related to research projects

Whilst not all of these examples clearly constitute falsification, fabrication or plagiarism, they have been identified in further work by the same authors (de Vries et al, 2006) as constituting the more common, but not condonable, questionable research practices; what the authors termed ‘normal misbehaviour’ (2006:48). The point of highlighting these behaviours here is that the behaviour compromises the integrity of the researchers’ work but seems to be almost ingrained with the everyday demands and ambiguities of scientific research which is difficult or even impossible, to regulate (de Vries et al, 2006). Alerting readers to these issues and behaviours would seem to be the first step in supporting a culture where these issues could be at least aired and discussed.

What isn't it?

Honest error or honest differences in the interpretation or judgment of data. Whilst honest error cannot be considered fraud there may still be misconduct issues that will require investigation, for example, if the errors were due to carelessness, inadequate or inappropriate procedures, training or supervision.

Why does it happen?

Although not a new phenomenon, increased reporting of scientific fraud has been noted since the 1970s and 1980s. Intense competition for funding from an increasing number of researchers at academic and other institutions and the necessity of publication for professional opportunity and promotion is thought to have led to an increase in research fraud (Claxton, 2005). At the very least such practices damage the reputation of and undermines the public support of science, and the reputation and standing of the University, and at its worst it puts others, namely research participants, at risk (Barrett, 2006).

What can be done?

The response from institutions and professional bodies was regulation – the production of guidelines, rules and recommendations -- rules for the investigation of misconduct and guidelines for good scientific practice which emphasise the responsibilities of researchers and scientific institutions (see below). These guidelines have demonstrated that it is the individual researchers themselves as well as academic institutions and publishers who have a collective responsibility for preventing, detecting and reporting research fraud.

What should I do if I suspect a colleague of research fraud?

The University, as your colleague's employer, is responsible for investigating misconduct. Other professional organisations may also be responsible for looking into your suspicions if they appear to involve professional misconduct.

The University’s document ‘Procedures for Investigation of Research Misconduct’ provides all necessary information and outlines the steps involved in reporting and investigating research misconduct. Details can be found at the following link: http://www.brunel.ac.uk/__data/assets/file/0007/383533/co18.pdf. If a colleague is not employed by the University, the above procedures should still be initiated but the research sponsor should also be informed.
What should I do if I suspect fraud through reading a paper in a journal?

The first step is usually to write a letter to the editor of the journal concerned voicing your concerns in as much detail as possible.

The Committee on Publication Ethics set up in 1997 have produced guidelines (Guidelines for Good Publication Practice, 2003) for authors, editors, readers and publishers to encourage a climate of intellectual honesty to inform publication ethics and prevent misconduct. The guidelines address issues such as study design, ethical approval, data analysis, authorship, conflict of interest, peer review and redundant publication and can be found at the flowing link: http://www.publicationethics.org.uk/guidelines.

For researchers working in the health and biomedical sciences the UniversitiesUK group (http://www.ukrio.org.uk) has established a panel to share experience and good practice although it has no powers to investigate. The Panel has reviewed existing codes and guidance documents and is producing a practical guidance document, The Code of Practice for Research. This will provide the research community with guidance on the definition and implications of research misconduct, and practical advice on the issues which need to be addressed to enable employers to effectively discharge their responsibilities. The Panel’s aim is to ensure that the most appropriate advice is available to those leading or managing investigations, as well as those who have concerns about the conduct of research.

A helpline - 0844 77 00 6 44 - is available between 8am and 8pm, Monday to Friday, with voicemail available at other times, and can also be e-mailed at helpline@ukrio.org. The service is confidential and is available to those working in the NHS as well as universities.

References


Good Practice Guidelines


British Psychological Society (2004) Ethical Principles for Conducting Research with Human Participants, Leicester, BPS.

British Sociological Association (2002) Statement of Ethical Practice, Durham, BSA.
Economic and Social Research Council (2006) Research Ethics Framework, Swindon, ESRC

Royal College of Physicians (2007) Guidelines on the Practice of Ethics Committees in Medical Research with Human Participants, London, RCP.

Data protection and the use of personal data in research

The Data Protection Act (DPA) 1998 governs the use of personal data.

Personal data is defined as data which relates to a living individual who can be identified from those data, or from those data and any other information which is in the possession of the data controller.

If research using personal data is being conducted by a student or member of staff of this University, then the data controller is the University.

When you collect and use personal data in your research, you must abide by the principles in the DPA. Briefly, these are:

Personal data shall

1. be processed fairly and lawfully;
2. be obtained only for one or more specified purposes, and not be used for other, incompatible purposes;
3. be adequate, relevant, and not excessive;
4. be accurate and kept up to date where necessary;
5. not be kept any longer than necessary;
6. be processed in accordance with the individual’s rights;
7. be protected against unauthorised or unlawful use, and against accidental loss or destruction;
8. not be transferred to a country which does not provide adequate protection for the individual’s rights and freedoms in relation to personal data. It is permitted to transfer personal data to any European Union country, Iceland, Norway, and Lichtenstein. In addition, Argentina, Canada, Switzerland, Guernsey, Jersey, and the Isle of Man have been deemed to provide adequate protection in this regard.

In order to collect and use personal data lawfully, you must either have the individual’s consent, or you must be able to prove that using the data is necessary for the “legitimate purposes of the data controller”.

To use personal data fairly, you must provide sufficient information to the individual so that they know why you want to use the data, who else might see them, and how long you will keep them.

There is a class of personal data which is called sensitive personal data, as follows:

- Racial or ethnic origin;
- Political opinions;
- Religious beliefs;
- Trade union membership;
- Physical or mental health or condition;
• Sexual life;
• Commission or alleged commission of an offence;
• Proceedings for any offence or alleged offense, the disposal of those proceedings, or the sentence of any court in those proceedings.

Before you can use any sensitive personal data, you must have the express (i.e., written or documented verbal) consent of the individual or a legally authorised representative, such as a parent or guardian.

Personal data, including sensitive personal data, may be used for research purposes as long as the following conditions are met:
• The data are not used to support decisions or measures relating to particular individuals;
• The data are not used in a way which causes substantial damage or distress to an individual.

As long as the data are used only for research purposes, they can be used for purposes other than that for which they were originally obtained. The data can also be held indefinitely.

In addition, the individual providing the data does not have the right of access to that data, as long as they are used only for research purposes and the results are anonymised (that is, the results do not identify individuals).

In general, if you wish to collect and use personal data or sensitive personal data for research, you should ensure you:
• Make it clear to the individual why you are collecting the data;
• Make sure you collect only the data you need;
• Give the individual the opportunity to opt out of the project if that is possible;
• Keep the data securely;
• Do not transfer the personal data outside the European Economic Area (EU, Norway, Lichtenstein, and Iceland) or to countries without adequate protection for personal data;
• Ensure your results are anonymised when they are reported.

Using personal data in research is very closely tied to the issue of consent.

Efforts are currently being made by various funding authorities to ensure that research data are made available to other researchers through various archives. It is not usually necessary to obtain consent for the use of anonymised data for another, different research project. However, if you are planning to deposit the data in an archive, or think it might be used by you or other researchers for another project, it is a good idea to include this on the information sheet and consent form.
References


JISC Data Protection Code of Practice for the HE and FE Sectors (http://www.jisclegal.ac.uk/publications/DPACodeofPractice.htm)

Information Commissioner's Office (http://www.ico.org.uk)
Research Participant Information Sheet

Potential recruits to your research study must be given sufficient information to allow them to decide whether or not they want to take part. The purpose of the project, and the fact that it is a research project, should be explained plainly and concisely. The nature of the project and all the technical terms and abbreviations should also be clearly explained. A translation should be provided if needed. An Information Sheet should contain information under the headings given below where appropriate, and in the order specified. It should be written in simple, non-technical terms and be easily understood by a layperson. Use short words, sentences and paragraphs, and remember that the Information Sheet should not be too long. The ‘readability’ of any text can be roughly estimated by the application of standard formulae. Checks on readability are provided in most word processing packages.

How much information? There are no specific legal criteria as to how much information is required for a research project. If invasive procedures are being used, the person should understand in broad terms the nature and purpose of the procedure and the material risks which are involved. Perhaps the best advice is that it would now be expected that the amount of information is enough for a reasonable participant to make the decision in hand. Clearly, this would involve a duty to warn of risks which a reasonable person might want to know in order to weigh risks and benefits.

In providing the above information, care should be taken to:

- give the prospective participant full opportunity and encouragement to ask questions;
- exclude the possibility of unjustified deception, undue influence and intimidation;
- seek consent only after a sufficient opportunity has been given to the prospective participant to consider whether or not to participate;
- as a general rule, but subject to exceptions, e.g., questionnaires, obtain from each prospective participant a signed form as evidence of consent;
- renew the consent if there are material changes in the conditions or procedures of the research.

Participant Information Sheets should appear on appropriately headed paper (usually bearing the Brunel University London logo), and should always contain Brunel University London, (not private) contact details of the researcher and (where relevant) the Supervisor.
The headings

- **Study title**
  
  Is the title self-explanatory to a layperson? If not, a simplified title should be included.

- **Invitation paragraph**
  
  This should explain that the person is being asked to take part in a research study. The following is a suitable example:

  ‘You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask me/us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

  Thank you for reading this.’

- **What is the purpose of the study?**
  
  The background and aim of the study should be given here. Also mention the duration of the study.

- **Why have I been chosen?**
  
  You should explain why and how the person was chosen and how many other participants will be involved.

- **Do I have to take part?**
  
  You should explain that taking part in the research is entirely voluntary. You could use the following paragraph:

  ‘As participation is entirely voluntary, it is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason.’

  Where relevant, it should be clearly stated that the right to withdraw at any time from the project will in no way influence or adversely affect the participant. A similar ‘no detriment’ statement may need to be included in the case of student participants.

- **What will happen to me if I take part?**
  
  You should say:

  - how long the person will be involved in the research;
  - how long the research will last (if this is different);
  - (where relevant) how often they will need to visit University premises/a clinic/day centre/school, etc., and how long these visits will be;
- whether travelling expenses will be available;
- what exactly will happen. e.g., tests, scans, x-rays, interviews etc.;
- what the participant’s responsibilities are;
- what you expect of them.

You should set out simply the research methods you intend to use. If interviews are involved, and will be recorded, you need to ensure this is specified on the consent form.

- **What do I have to do?**

  Are there any lifestyle restrictions? You should tell the person if there are any dietary restrictions. Can the person drive? drink? take part in sport? Can the person continue to take their regular medication? Should the participant refrain from giving blood? What happens if the participant becomes pregnant?

- **What are the possible disadvantages and risks of taking part?**

  Here, a simple statement of risk should be included, bearing in mind that ‘no risk’ is likely to be the case in extremely exceptional circumstances. Any material risks, side effects or discomforts should be clearly indicated. If there is any possibility of psychological distress, you should mention this as well.

- **What are the possible benefits of taking part?**

  Where there is no intended benefit to the person from taking part in the study, this should be stated clearly.

  It is important not to exaggerate the possible benefits to the particular person during the course of the study, e.g., by saying they will be given extra attention. This could be seen as coercive.

- **What if something goes wrong?**

  You should inform people how complaints will be handled and what redress may be available. Is there a procedure in place? In relation to the NHS LREC form, you will need to distinguish between complaints from participants as to their treatment by members of staff (doctors, nurses, etc.) and something serious happening during or following their participation in the research, i.e., a reportable serious adverse event.

  Where the study carries risk of physical or significant psychological harm, the following (or similar) should be said:

  ‘If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone’s negligence, then you may have grounds for a legal action but you may have to pay for it.’

  The person to be contacted if the participant wishes to complain about the experience should be the Chair of the principal investigator’s
College Research Ethics Committee. Refer to the flow chart at the end of this section.

- **Will my taking part in this study be kept confidential?**

  You may need to obtain the person’s permission to allow restricted access to their records/files/notes and to the information collected about them in the course of the study. You should explain that all information collected about them will be kept strictly confidential.

  The following form of words might prove useful:

  ‘All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the University/hospital/surgery/local authority premises, etc., will have your name and address removed so that you cannot be identified from it.’

  You should always bear in mind that you, as the researcher, are responsible for ensuring that when collecting or using data, you are not contravening the legal or regulatory requirements in any part of the UK.

  Please refer to information below regarding the difference between confidentiality and anonymity.

- **What will happen to the results of the research study?**

  You should be able to tell the participants what will happen to the results of the research. When are the results likely to be published? Where can they obtain a copy of the published results? You might add that they will not be identified in any report/publication.

- **Who is organising and funding the research?**

  The answer should include the organisation or company sponsoring or funding the research (e.g., ESRC, company, charity, academic institution).

- **What are the indemnity arrangements?**

  Participants should be informed if participation in a study might affect health-related insurance.

- **Who has reviewed the study?**

  You must give the name of the Research Ethics Committee which reviewed the study.

- **Contact for Further Information**

  You should give the person contact points for further information (see above).

  Remember to thank the individual for taking part in this study!

The Participant Information Sheet should state that the individual will be given a copy of the information sheet and a signed consent form to keep.
To test the literacy level of your information sheet, check the SMOG calculator (http://www.harrymclaughlin.com/SMOG.htm).
**Recruitment of participants**

For researchers wishing to use human participants, recruitment can be one of the most difficult aspects of the project.

**Inappropriate methods**

You may think the easiest way to accomplish recruitment is to send an e-mail to, say, all current students, or all staff. However, there are reasons to avoid the temptation of taking the easy route.

Essentially, any e-mail that is sent to large numbers of recipients, when many or all of those recipients are unknown to you, is SPAM. If you do this using your Brunel account, you are in violation of the Brunel Acceptable Computer Use Policy (BACUP) and could find your account suspended as a result.

It is especially inappropriate to send an e-mail by copying large portions of the Outlook address book into the To field.

This scattergun effect is more likely to irritate the recipients than persuade them to participate in your project.

**Preferred methods for Brunel participants**

You can use submit a Research Participation Invitation (RPI) through IntraBrunel. You need to provide:

- your name;
- your College;
- a brief description of the research and who can participate;
- a way for potential participants to contact you;
- the name of the REC which approved the project;
- the date of the REC approval;
- the start and end dates when your advertisement should be visible on IntraBrunel.

You can use posters which include a short description of the project, and your Brunel contact details, to alert people of the opportunity to take part. Make sure you include a statement to the effect that you have obtained ethical approval for the project.

If you wish to target a particular group, for example, 3rd-year students taking a particular module, then see if you can take 5 minutes of time from a lecture to speak to the group about the project and ask for participation.

If you want participants from a specific cohort, you may be able to use e-Vision to send a Department letter to each student. (Refer to the SITS Support Team for more details [http://intranet.brunel.ac.uk/registry/SITS/home.htm](http://intranet.brunel.ac.uk/registry/SITS/home.htm)). Student researchers will need to request help from a College administrator for this.
To request participation from staff in a particular College or department, it is recommended that you ask the College Director of Operations or Head of Department to send an e-mail to their staff.

It may also be possible to put a short paragraph on your College intranet page.

Regardless of which method you use, you should include a short summary of the project and either your Brunel contact details, or a link to a webpage where more information may be found.

**Non-Brunel participants**

If you intend to seek participants from outside the University, it is usually most efficient to go through a gatekeeper in the particular organisation you wish to target.

Of course, it’s also possible to buttonhole people on the street and ask if they wish to participate. If you choose this method, be aware that any subsequent e-mail communication should not be sent to a group; your participants may not be happy to have their e-mail addresses passed on to the other participants. You should also ensure that your contact details are not your home e-mail or snail mail address, your home phone number, or your personal mobile number if at all possible.
**Risk Assessment**

In designing any research project one must pay proper attention to any risks that may occur. These include risks to participants and risks to which the researchers themselves may be exposed. In all cases it is the responsibility of the researcher to identify risks and propose mitigating actions. Some risks will fall into the category of “health and safety” and here standard procedures laid down by the University should be followed. Other risks will be less clearly demarcated, and experience suggests that risks to the researchers themselves are sometimes overlooked.

It is important when assessing risks to consider not only the likelihood of them occurring, but their impact upon the project, researcher or participants. Having identified a risk then one should also decide what actions have (or will) be taken in order to lessen the likelihood that the event will occur, or to reduce the impact if it does. It is worth appreciating that people vary widely in their attitude to risk, and this may lead researchers in particular to accept levels of risk that are higher than desirable, either because they are in a hurry to get the job done and do not wish to change any plans or because they are highly motivated to undertake the research and will accept high personal risk factors, or sometimes just because they are inexperienced. It is thus helpful for risks be discussed within the project team as widely as practical.

Should your project include human participants, the College and/or University Research Ethics Committee will closely examine the potential risks, and may request more robust control measures. If the risks are deemed to be of sufficient severity, either to the participants or the researcher(s), ethical approval may be withheld.

**Risk Assessment Resources**

**Health and Safety**

There are a number of policies and procedures available on the University's intranet site ([https://intra.brunel.ac.uk/s/operations/hands/Pages/default.aspx](https://intra.brunel.ac.uk/s/operations/hands/Pages/default.aspx)). Besides the general health and safety policy, there are policies which deal with using hazardous substances, disposing of waste (which may be hazardous) and a general risk management policy.

**Radiation and Biological Safety**

These pages ([https://intra.brunel.ac.uk/s/operations/hands/Pages/Radiationsafety.aspx](https://intra.brunel.ac.uk/s/operations/hands/Pages/Radiationsafety.aspx) and [https://intra.brunel.ac.uk/s/operations/hands/Pages/Biologicalsafety.aspx](https://intra.brunel.ac.uk/s/operations/hands/Pages/Biologicalsafety.aspx)) provide information, policies and procedures related to the use of radioactive, chemical, or biological substances.

**Joint Information Systems Committee (JISC)**

A very useful resource that covers many aspects of risk management is provided by JISC via their InfoNet service and is available here: [http://www.jiscinfonet.ac.uk/InfoKits/risk-management](http://www.jiscinfonet.ac.uk/InfoKits/risk-management).
What is the supervisor’s role in the research ethics process?

The research supervisor should be aware of the requirements for research ethics approval.

The research supervisor should be able to support the student through the research ethics application process. This means the supervisor should:

- be conversant with University policies, procedures and guidance documents
- help the student determine whether a risk assessment should be conducted and direct the student towards the appropriate documentation and other resources within the University
- be aware of documents produced by relevant organisations and professional bodies
- alert the student to the relevant documents, policies and procedures
- remind students of their responsibilities with reference to the student handbook
- provide support to the student, outline common pitfalls, provide examples of good practice, discuss difficult issues
- sign appropriate documents
- provide the supervisor’s contact details for participant information sheets so that participants can contact the supervisor to discuss issues or complaints about the research.

Once the application has been approved the supervisor should anticipate and encourage discussion of research ethics issues during the research process, including during data collection and writing up.

The research supervisor should follow up research ethics issues on completion of the study; for example the supervisor should

- remind the student of responsibilities regarding storage and destruction of data
- organise custodianship of data if required.