Kirklees College

Higher Education

Research and Ethics policy

Document: Higher Education **Research and Ethics Policy**	
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Contents

1. Definition of Research

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

1.1. Definition Of Research Requiring An Ethical Review

All Kirklees College research requires ethical review and clearance through the procedure set out in Section 5 of this policy. The only exceptions to this rule are listed in Sections 1.2 and 1.3 below.

This includes all research that involves human or animal participants, either as direct participants, or through their provision of or access to personal data, or through their involvement on behalf of others.

Ethical approval is also required for research that does not directly involve human or animal participants but does raise other ethical issues due to the potential social or environmental implications of the study. The re-use of personal data may also require ethical approval due to its sensitive nature or if individuals can be identified from it.

It is the responsibility of the researcher (if a member of staff) and of the appropriate Award Leader (if the researcher is a student) to determine whether the work in question is research and to ensure that the proposal is submitted for ethical review before work commences.

1.2. Definition of Research NOT Requiring An Ethical Review

Research that does not require ethical review is research that:

- Does not involve human or animal participants (see Appendix A.5 for definition of human participants, including personal data and involvement on behalf of others), and
- Does not involve potential physical or psychological risk to the researcher(s),
- Does not present a risk to the environment, and
- Does not involve confidential or sensitive data (see Appendix A.7 for definition of sensitive data)

These projects will usually be entirely desk and/or library-based**.** Any student research that does not meet these conditions must be submitted for ethical review and approval through the process outlined in Section 5.

2. Key Principles of Ethical Research

Principle 1

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

Principle 2

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

Principle 3

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

Principle 4

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

Principle 5

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

Principle 6

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

3. Levels of Ethical Review

The College has a tiered approach to research ethics review, according to the level of risk involved.

3.1. No apparent risk:

This applies only to the research outlined in 1.2 above. In this case, the responsible member of staff keeps a record of the ethical status of the research. This is the only instance where a Request for Ethical Approval is not obligatory.

3.2. Low risk:

This includes research where human participants are involved, but none of the additional risk areas on the Request for Ethical Approval are applicable to the research in question. For instance, human participants may be involved, but they are not from vulnerable groups or their gatekeepers, and the other listed risks do not apply.

Low risk research may be undertaken by staff, students or external researchers. In all cases, an Request for Ethical Approval should be filled out and submitted to a member for staff for approval in order to demonstrate awareness of potential ethical issues and how the researcher will ensure conformity with Kirklees College's research ethics principles (see Section 2 above), even if there are no obvious ethical issues. Low risk research by students, staff or external researchers is usually approved by a relevant member of staff rather than the Research Ethics Committee.

3.3. Student research that forms part of a taught course: Some College courses have a structured and supervised research component, where all students undertake similar research at a particular stage in their studies. Where this is the case, the course leader/programme manager must present the course/research programme to the College's Research Ethics Committee (REC), highlighting all areas of potential risk. The Committee may then approve members of course staff to provide ethical review and release within agreed boundaries. Once general approval has been given by the Committee, a Request for Ethical Approval is completed by each individual student and approved within the relevant department by agreed members of staff. Any individual project that exceeds the agreed boundaries for this form of consent must be referred to the Research Ethics Committee.

3.4. Higher risk: The following research must be submitted to the Research Ethics Committee:

- Research involving potentially vulnerable groups and/or their gatekeepers (See Appendix A.8)
- Research involving sensitive topics
- Research without prior consent (See Appendix A.1 and A.5)
- Research using administrative data or secure data (See Appendix A.2 and A.7)
- Research involving access to records of personal or sensitive confidential information (See Appendix A.2 and A.7 on data, and A.5 on retrospective consent)
- Research which might induce physical harm or psychological stress
- Research involving intrusive interventions or data collections methods (e.g. vigorous exercise, administration of substances, disclosure of normally private information, repetitive testing)
- Research where the safety of the researcher may be in question
- Research undertaken outside the UK where there may be issues of local practice and political sensitivities

- Research involving respondents through the internet, in particular where visual images are used, and where sensitive issues are discussed
- Other research involving visual/vocal methods where individuals may be identifiable
- Research which may involve data sharing of confidential information beyond the initial consent given
- Research which may harm the environment
- Research where there is conflict of interest or financial inducement
- Research which includes the use of control groups

These categories are set out as a Request for Ethical Approval that all researchers must fill in prior to submitting their proposal for ethical review.

Where one or more of the above criteria apply, the researcher must complete the Request for Ethical Approval and have it checked and countersigned by an approved member of staff. The Checklist is then sent to the Research Ethics Committee.

The Role of the Ethics Committee

The Kirklees College Research Ethics Committee (REC) is responsible for undertaking the ethical review of research and scholarly projects which pose potential risk.

The primary role of the Kirklees REC is to protect the dignity, rights and welfare of research participants and the safety of researchers. It also gives due regard to the consequences of the proposed research for others directly affected by the research and to the interests of those who do not take part in the research but who might benefit or suffer from its outcomes in the future.

The REC aims to be free from bias. REC members must inform the Chair if they have a financial or personal interest in a project or with a project sponsor. The Chair will decide whether the interest disqualifies the member from the discussion. The REC will regularly monitor the decisions taken.

The REC maintains a record of all ethics submissions and responses, whether these are light touch or full ethical review.

3.5. Membership of the Ethics Committee

The College REC will aim to have members with broad experience in the areas of research and who have the confidence and esteem of the college research community and with knowledge of ethics and related issues. The Committee can co-opt an appropriate member of staff and/or seek advice of an independent researcher where the REC needs a greater understanding of the scientific or scholarly merit of a proposal.

Chair: Quality Leader Higher Education

Members: Head of Quality, Higher Education and Teacher Education. Other members may be co-opted as necessary to one meeting or more

Officers: Higher Education Administrator

Staff and students may be required to attend the College Research Ethics Committee when their research proposals and other matters relating to the ethics of their research are being discussed.

3.6. Decisions made by the Research Ethics Committee

Approval

Research Request for Ethical Approval If the REC approves the course research programme, named staff can provide ethical release for each student project carried out on the course through the agreed procedure. A copy of each students checklist and ethical release form must be kept by the Department in question and be available for audit by the REC

Approval with conditions

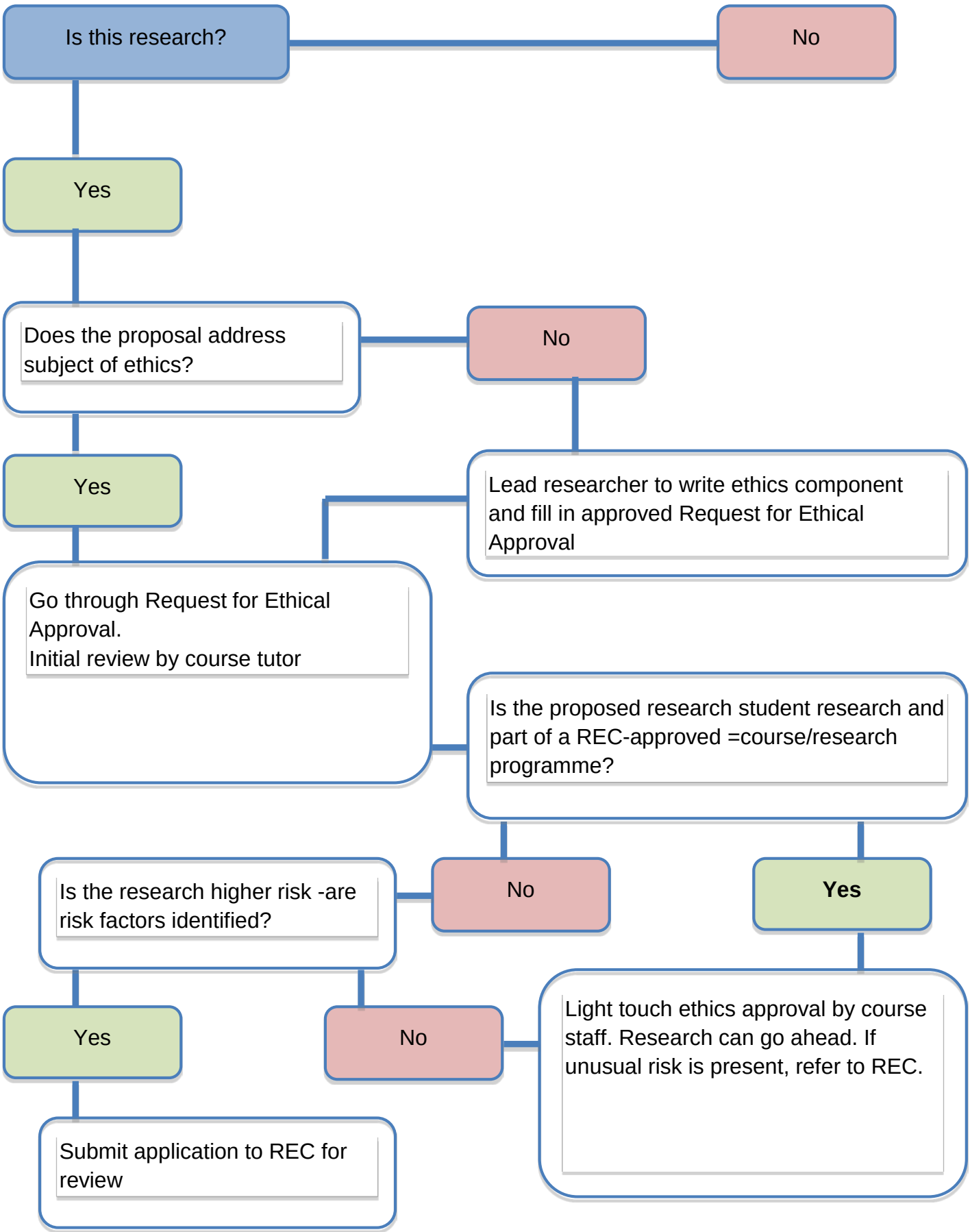
The REC may request that certain conditions are met or modifications made. Compliance with this is expected as part of the research ethics approval process

Rejection

In rare circumstances, where a programme of research presents a significant risk, the REC may require its suspension or significant modification

Ethics approval granted by the REC for a specific course research lasts 6 years. Any significant changes to the research programme should be notified to the REC and may require new application for ethics approval.

4. Research Project Approval Process



Research Request for Ethical Approval/ Review Form for Staff

All research at Kirklees College conducted by students, staff and external researchers must go through an ethical review procedure before it begins; including all research that involves human participants. The only exception to this is desk-based research at undergraduate level or below, that does not involve sensitive or confidential information.

Ethical Review Application Form

REQUEST FOR ETHICAL APPROVAL – CONFIDENTIAL **Please return completed form to:** **The HE Administrator** **Research Ethics Committee** **Higher Education Department** ***You must answer every question. Incomplete forms will be rejected***		
Name(s) of researcher(s)/student(s) working on this project:		
Name of course		
Project title		
Name of project supervisor:		
Expected duration of project *Note: projects can be audited at any point during the length of the project following ethical Clearance*	From	To
Basic aim(s) of project (word count – 300 words):		
Does this project involve the recruitment of **human participants** for data collection or the collection of samples from human subjects	Yes	No
If NO, then go to SECTION B		

SECTION A (complete ONLY if using human participants)				
1.	Does the research involve	Kirklees College Students or staff	YES	NO
		Members of the public over the age of 18	YES	NO
		Members of the public between 16-18 years of age	YES	NO
		Children, under the age of 16 – Indicate age range	YES	NO
		Elderly people	YES	NO
		Vulnerable adults	YES	NO
		Patients of drug or alcohol rehabilitation clinics	YES	NO
2.	How many participants will be involved?			
3.	What are the criteria for selection? How will participants be selected?			
4.	Will this project involve randomisation and/or use of control groups?		YES	NO
If YES, please describe how these procedures will be administered				
5.	Does this project involve any physical interventions or methods, such as participants ingesting substances, being given physical treatments, or performing physically		YES	NO

	demanding activities?		
If YES, please describe these procedures or activities:			
6.	Does this project involve asking human participants questions as part of a survey, or asking for human participants' involvement in focus groups, case studies, or to be subjects of ethnography or any form of surveillance?	YES	NO
If YES, describe the full range of topic(s) that participants will be asked about (be specific – 500 words):			
7.	What steps (if any) will be taken if previously unknown factors become known to the researcher during the course of questioning which may require disclosure to the participant, another professional, the police or other authorities? 300 words:		

8. What are the risks to participants because of the research design and/or methods? ***(indicate all that apply):***	physical injury	YES	NO
	side effects due to ingestion of substances or other invasive procedures	YES	NO
	psychological or emotional distress	YES	NO
	significant discomfort or inconvenience, whether physical or emotional	YES	NO
	damage to a participant's personal reputation due to disclosure of personal details other (describe):	YES	NO

9. Will informed consent be obtained from all participants? ***(If written, attach a copy of the consent form to be given participants to gain consent)***	YES	NO

If NO, why not? (Provide rationale.)	
10. What information will be given to subject(s)? *(Attach copies of letters or information sheets to be given to participants.)*	

11.	Is there doubt as to a subject's ability to give consent?	YES	NO
If YES , what steps will be taken to ensure that the subject is willing to participate *NOTE: If participant(s) would be defined as being "without mental capacity" under the conditions set by the Mental Capacity Act 2005, then approval for your project cannot be granted by the College.*			
12.	Are children under the age of 16 involved in the research?	YES	NO
If YES how will consent be obtained from parents/guardians and assent from the children and how and where will consent be recorded?			
13.	Will participants be informed of their right to withdraw?	YES	NO
If NO, why not? If YES, will there be a limit on the period of time in which withdrawal will be allowed? give length of time limit and rationale for time limit on withdrawal:			

14.	What steps and procedures will be taken to preserve the confidentiality of participants' identities, information, or data of any kind used in the project?		
15.	Do you foresee any circumstances under which confidentiality may need to be breached?	YES	NO
If YES, what circumstances are possible and what steps would be followed to deal with breach of confidentiality?			
16.	Will any secondary analysis of data occur during the project (i.e.: data previously collected by research not as part of the current project)?	YES	NO
If YES – will this data previously have been anonymised?		YES	NO
If NO – what steps will be taken to ensure that consent for the uses to which unanonymised data will be put in secondary analysis do not contravene the General Data Protection Regulations (2018)			

SECTION B TO BE COMPLETED IF THE RESEARCH INCLUDES HUMAN OR ANIMAL PARTICIPANTS			
17.	What risks are there to the researcher(s)/student(s) conducting the project? If NONE, write NONE		
18.	What risks are there to animals, property, facilities, or the environment during conduct of the project? If none, write 'NONE'		
19.	Will the research make use of any of the following: human/animal blood, semen, saliva, urine, bodily fluids or human/animal tissue of any kind?	YES	NO
20.	If YES, what steps will be taken to ensure that the research is not in contravention of the Human Tissue Act 2004? or the Animal Welfare Act (2006)? *PLEASE NOTE No project will be approved that contravenes the Human Tissue Act 2004 or the Animal Welfare Act (2006)*		
21.	Will the project receive financial support from outside Kirklees College?	YES	NO
22.	If YES, specify the nature and source of the support:		

23. Will any restrictions be placed on the publication or use of research results?	YES	NO
If YES, please state the nature of the restrictions:		
24. Are there any further points you would like to make in support of the proposal?		
I understand that the ethical propriety of this project may be monitored and that my project may be audited by the Kirklees College Research Ethics Committee *at any time during the course of the project*.		
Signature of researcher	Signature of supervisor	

Decisions made by the Research Ethics Committee (REC)

Name of Student: **Date:**

Approval ☐

Approval with conditions ☐

The REC may request that certain conditions are met or modifications made. Compliance with this is expected as part of the research ethics approval process

Rejection ☐

In rare circumstances, where a programme of research presents a significant risk, the REC may require its suspension or significant modification

Ethics approval granted by the REC for a specific course research lasts 6 years. Any significant changes to the research programme should be notified to the REC and may require new application for ethics approval.

Signed Chair or REC **Date**

Appendices

A1 Consent

Informed consent has two components, which are of equal importance. The first is that a prospective participant, prior to participating in research, should be fully informed about all aspects of the research project in which s/he is considering participating that might reasonably be expected to influence his/her willingness to participate. The researcher should explain any other aspects of the research about which prospective participants may enquire.

The second component of informed consent is that potential participants should be able, freely and voluntarily, to consent or refuse to participate in research. Under no circumstances must direct coercion or indirect pressure be used to obtain a person´s consent to participate in research.

There are a number of specific situations where the securing of consent is more complex or more sensitive, for instance with regard to children and vulnerable adults. Researchers should secure expert advice in these cases.

A2 Data

Data are important in the context of ethical review. Data related to individuals needs to be handled carefully and in accordance with relevant legislation. The confidentiality of participants in research (or other activity as appropriate) should always be maintained and the privacy of participants should be protected in any publication arising from the research in line with current best practice.

The Ethics Policy uses as a guideline the General Data Protection Regulation (2018) definition of personal data:

"'personal data' means any information relating to an identified or identifiable natural person ('data subject')". It adds that:

"an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location number, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person."

A3 Ethics

General ethical principles adopt the values of 'doing positive good' and 'the avoidance of harm' and these should be at the heart of any ethical consideration.

A4 Misconduct in Research

The UK Research and Integrity Office (UKRIO) defines misconduct in research as including, but not limited to:

1. Fabrication;
2. Falsification;
3. Misrepresentation of data and/or interests and/or involvement;
4. Plagiarism; and
5. Failures to follow accepted procedures or to exercise due care in carrying out responsibilities for:

    a. avoiding unreasonable risk or harm to:
        i. humans;
        ii. animals used in research; and
        iii. the environment; and
    b. the proper handling of privileged or private information on individuals collected during the research.

Misconduct in research can occur by commission or omission. The failure to submit appropriate research to ethical review constitutes potential grounds for misconduct.

A5 Research Involving Human or Animal Participants

Research involving human participants must always be subjected to ethical scrutiny, to ensure it is carried out in a way that reduces the risk of harm to the participants and increases the potential for benefit. Such benefit may mean, for example, the advancement of knowledge, or the educational benefit of a student.

Research involving human participants is defined broadly to include research that:

(i) directly involves people in the research activities, through their physical participation. Physical participation may include invasive (e.g. surgery) and / or non-invasive research (e.g. interviews, questionnaires, surveys, observational research) and may mean the active or passive involvement of a person;

(ii) indirectly involves people in the research activities, through their provision of or access to personal data and / or tissue;

(iii) involves people on behalf of others (e.g. parents / legal guardians of children and the psychologically and / or physically impaired, and supervisors of people under controlled environments

A5 Retrospective Consent

Normally, written consent is secured from participants in advance of their active involvement in research. Occasionally, this is secured afterwards. Retrospective consent is required only in limited circumstances, for instance:

- With regard to data submitted for a different original purpose where anonymity and confidentiality have been assured. The researcher must secure informed consent to use this data for other research purposes. Note that in addition to the Data Protection Act, the common law duty of confidence applies to research, as to all other activities. Individuals have a reasonable expectation of privacy with respect to confidential information that refers to them. Any use of such confidential information that exceeds that which an ordinary person could reasonably be said to expect constitutes a breach of confidence.

- With regard to people who, despite their not having been direct participants in a research project, may be named or otherwise referred to, in publications arising from the research. In such circumstances, unless it is a matter of a public person acting in her/his public capacity, the researcher(s) must either (1) anonymise the person, so that they cannot be identified, or (2) ensure that they have obtained the consent of the individual concerned.

- In some contexts, it may be appropriate to secure consent both in advance and retrospectively – for instance, there is a `grey area´ with respect to consent in ethnographic research, particularly participant observation in which the researcher sets out to become a part of the social setting that is the context or focus of the research. This is an established research approach, but it entails risks of misunderstanding that underline the need to regard consent as an ongoing process of negotiation and discussion. Research with a strong community dimension may benefit from repeated dialogue with participants regarding the progress of the research and their rights within it.

- In certain types of research obtaining consent from every individual present is neither practical nor feasible (e.g. observing behaviour in public places, attending large meetings, observing discussions on the internet). Research of this kind stretches the definition of what it actually means to be a human participant in research. In research of this kind researchers should ensure the following:

- that such research is only carried out in public contexts, defined as settings which do not require any particular negotiations or agreements in order to gain access to them;
- that, if relevant, approval is sought from the relevant authorities;
- that, if relevant, appropriate stakeholders are informed that the research is taking place;
- that specific individuals should not be identified, explicitly or by implication, in any reporting of the research, other than public figures acting in their public capacity (as in reporting a speech by a named individual, for example); and that attention is paid to local cultural values and to the possibility of being perceived as intruding upon, or invading the privacy of, people who, despite being in an open public space, may feel they are unobserved.

A6 Sensitive Personal Data

Particular care should be taken when collecting or storing sensitive personal data, which in the 2018 Regulations is defined as consisting of information as to:

(i) the racial or ethnic origin of the data subject;
(ii) his or her political opinions;
(iii) his or her religious beliefs or other beliefs of a similar nature;
(iv) whether he or she is a member of a trade union (within the meaning of the Trade Union and Labour Relations (Consolidation) Act 1992);
(v) his or her physical or mental health or condition;
(vi) his or her sexual life;
(vii) the commission or alleged commission by him or her of any offence; and/or any proceedings for any offence committed or alleged to have been committed by him or her, the disposal of such proceedings or the sentence of any court in such proceedings'. (Source: GDPR 2018)

Care should also be taken when collecting and storing sensitive personal data in order that participants cannot be identified indirectly - for example through the use of date of birth and postcode information.

A7 Vulnerable Groups

Among the categories of people who are perceived to be likely to be particularly vulnerable research participants are:

(a) People whose competence to exercise informed consent is in doubt, such as:

- infants and children under 18 years of age;
- people who lack mental capacity;
- people who suffer from psychiatric or personality disorders, including those conditions in which capacity to consent may fluctuate; and

- people who may have only a basic or elementary knowledge of the language in which the research is conducted.

(b) People who may socially not be in a position to exercise unfettered informed consent, such as:

- people who depend on the protection of, or are controlled and influenced by, research gatekeepers (e.g. school pupils, children and young people in care, members of the armed forces, young offenders, prisoners, asylum seekers, organisational employees);
- family members of the researcher(s); and
- in general, people who appear to feel they have no real choice on whether or not to participate.

(c) People whose circumstances may unduly influence their decisions to consent, such as:

- people with disabilities;
- people who are frail or in poor health;
- relatives and friends of participants considered to be vulnerable;
- people who feel that participation will result in access to better treatment and/or support for them or others;
- people who anticipate any other perceived benefits of participation; and
- people who, by participating in research, can obtain perceived and/or real benefits to which they otherwise would not have access.