INFORMED CONSENT GUIDELINES

1. INTRODUCTION

These guidelines have been developed by University Research Ethics Committee to promote good practice in research projects and engagement activities which involve working with human participants. The aim of this document is to provide guidance to University colleagues and students on how to obtain informed consent, and signpost towards sources of further information. This document will be regularly reviewed and updated to reflect current best practice.

2. DEFINITION

The term 'Informed Consent' refers to the process of informing potential participants of the purpose, methods and intended use of the research, to enable them to make an informed decision about whether or not to take part in the project. To ensure that participation is voluntary, participants should have the opportunity to ask questions as part of the decision-making process. If they agree to take part, evidence of informed consent should be formally recorded.

3. KEY PRINCIPLES

3.1 Understanding the risks and the benefits

The primary objective of informed consent is to be open with potential participants about the details of the study, and the potential risks and benefits of their involvement. Potential risks may include:

a) Physical risks: taking part in intrusive, invasive or potentially harmful procedures which may involve pain/discomfort or other side effects.

b) Emotional risks: taking part in interviews or focus groups which involve the discussion of sensitive topics.

Potential participants should fully understand the risks involved, so that they can make a balanced decision about whether or not to take part.

3.2 Voluntary participation

a) Free from coercion: the decision to take part in a project or activity should always be made voluntarily. Researchers should be aware of any power dynamics that may affect voluntary participation. For example, stateless persons or offenders in UK prison institutions may feel under pressure to participate in a research project due to their status. If internal colleagues and students are approached to take part in a research project at Newcastle University, the decision not to participate should not have any impact on their employment or studies.

b) Use of a gatekeeper: recruitment strategies involving the use of a third party or 'gatekeeper' to access participants should also be considered carefully to avoid any forms of coercion.

Examples of gatekeepers include:

- Teachers at schools and other educational institutions
- Hospital staff

- General Practitioner (GP) services
- Other providers of health and social care services
- UK HM Prison Services

c) <u>Financial rewards and inducements</u>: may be used to encourage participation or compensate travel expenses. However, payments should not be used to induce participants to risk harm beyond the risks they would normally encounter in their day-to-day activities. Faculty Ethics Committees can offer advice to applicants on what constitutes a reasonable amount as part of the University's ethical review process. NHS Research Ethics Committees provide similar advice on healthcare research projects that require external approval, such as Clinical Trials of Medicinal Investigational Products (CTIMPs).

3.3 Right to withdraw

Ideally, participants should have the right to withdraw at any point in the study without any negative repercussions. If a participant chooses to withdraw, any personal data or tissue that has been collected should be destroyed. If this is not possible, researchers should make sure that potential participants are aware of this during the recruitment process, as well as the rationale for the decision.

3.4 Vulnerable groups

Special care should be taken when working with individuals or groups who may be vulnerable due to their age, disability, their physical or mental health. This is because they may not be able to fully understand the nature of the research, or what their participation will involve. However, valuable data may be obtained by conducting research with these participants, which may lead to the development of novel interventions, products and services.

Ethical approval for these types of studies will be provided on the basis that the methodology is designed to protect the dignity, rights and wellbeing of participants, and ensure that their interests are best served. For example, under the guidance and supervision of expert intermediaries.

4. PROCESS OF OBTAINING CONSENT

4.1 Providing information about the study

During the recruitment process, potential participants should be provided with details of the study. This information is usually provided in the form of a written document or **Participant Information Sheet (PIS)**, which the individual can take away and read. Simple language should be used to ensure that the information is understood by a lay audience, including a clear description of any terminology.

The layout of a Participant Information Sheet should be appropriate to the type of study and intended audience. Although the document should cover the following points:

- Project title.

- Project summary, including the aims and objectives of the study, how the project is funded and the publication strategy.

- Information about the project team, including their institutional affiliations, relevant qualifications and training.

- Participant criteria e.g. age range, gender, ethnic group.

- Details of what will happen to participants during the study, including the potential risks and benefits of taking part.

- Information about how any data / tissue samples will be used and / or shared with third parties.

- Details of how confidentiality and anonymity will be preserved. Including any limitations to confidentiality e.g. in the event of any safeguarding concerns.

- Statement regarding voluntary participation and the right to withdraw. Including information about what will happen to any data / tissue samples if the participant chooses to withdraw.

- A named contact for questions, comments and complaints.

- The name of the Ethics Committee that has approved the project and the approval date.

- The version number and date of the document.

Researchers should also consider producing different versions of Participant Information Sheets for speakers of different languages, or for different age groups.

Depending on the nature of the study, information may also be provided to participants verbally. This approach may be the most appropriate way of providing information to vulnerable individuals, or in clinical intervention studies. To ensure standardisation, a text version of the script should be produced and shared with the relevant Ethics Committee as a supporting document.

The intended use of any personal or sensitive data should be provided in a **Privacy Notice**, summarising how the data will be processed. Researchers should be aware of the difference between consent to participate in a research study and consent to store and process data under the UK General Data Protection Regulation. As Newcastle University is a public funded organisation, participants should be advised that the legal basis for collecting and processing data is research conducted in the public interest.   Principles of consent also apply to possible reuse of data. If the results of the study will be published, the Privacy Notice should also include a statement regarding the sharing of underpinning data in accordance with the University's Institutional Position Statement on Open Research.

4.2 Obtaining consent

There are three different approaches that can be used to obtain consent from participants:

1) Implied consent: where consent which is not expressly granted by a person, but can be assumed through their actions, or the facts and circumstances of a the situation. For example, by agreeing to stop and talk to an interviewer in the street, or by completing an online survey.

2) Verbal consent: where consent is expressly granted verbally. For example, prior to taking part in an online interview. Evidence of verbal consent should be captured in an audio or video recording.

3) Written consent: where consent is expressly granted in writing. Either by signing a **Consent Form** or by making a formal declaration by email.

Please refer to Section 6.2 for further guidance on which approach may be appropriate for different types of studies. However, for research activities, the University recommends that written consent should be obtained from participants where possible. A witness should also be asked to countersign a Consent Form for high-risk projects such as studies involving vulnerable groups or clinical research involving invasive procedures. Two copies of the Consent Form should be signed by the participant. One copy should be retained by the researcher and one copy retained by the participant for their information.

4.3   Special considerations

a)   <u>Working with children and young people</u>**:** in the UK, children and young people under the age of 18 are legally considered minors. However under common law, young people aged 16-18 with sufficient understanding are able to give their full consent to participate in research projects without parental consent. In accordance with the [Gillick Principle](#), a competent minor may also consent to participate in research. Although the involvement of a parent or legal guardian is encouraged in the decision-making process, and their assent should also be recorded. To aid understanding, a Participant Information Sheet should be written in language which is appropriate for the age group. Pictures may also be used to explain terminology or illustrate a procedure. Research involving children outside the UK should abide by the legal age of consent and accepted local practices within that country.

b)   <u>Working with adults at risk of harm</u>**:** the Mental Capacity Act sets out the legal framework for the conduct of research with adults with a diagnosed cognitive impairment. By law, there must be a clear justification for carrying out intrusive research[1] with people who lack the capacity to consent. For example, the research must be connected with the impairing condition or its treatment. In which case, there are clear benefits to the individual taking part in the research, which could not be achieved if they were excluded.

When working with vulnerable groups, researchers should assume that individuals have the capacity to consent unless established otherwise. Capacity may be established by conducting the following **two-step assessment**:

1) Does the person have an impairment of the mind or brain, or is there some sort of temporary / permanent disturbance affecting the way their mind or brain works?

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

In accordance with the [Mental Capacity Act Code of Conduct](#), a person is unable to make a decision if they cannot:

- Understand the information relevant to the decision
- Retain the information
- Use or weigh the information
- Communicate their decision by any means

If the assessment confirms that the individual does not have the capacity to consent, the Code of Conduct also sets out an approach that can be taken to include them in the research. Researchers are required to seek advice from a consultee on what the wishes and feelings of the person might be, and whether or not they would want to take part in the study. Although they consultee can offer advice, they are not able to provide consent on behalf of the participant. All possible steps should be taken to help the individual to understand the information and make a decision for themselves.

Due to the complex legal and ethical considerations which apply to this type of research, all studies involving participants who lack capacity to consent must be approved externally by an NHS Research Ethics Committee.

For further guidance, please refer to the Health Research Authority (HRA) e-learning module on [research involving participants lacking mental capacity](#) (registration required).

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[1] Defined under the Mental Capacity Act as research which would normally require an individual's consent to involve them.

4.4 Obtaining consent retrospectively

Informed consent refers to the process of obtaining consent prior to the collection of data. However, Ethics Committees will consider the rationale for studies involving different approaches alongside other ethical considerations of the research design and methodology. For example, psychology projects which involve the use of covert observation or deception in order to observe people's natural behaviour. In these types of studies, a **Debriefing Sheet** should be provided to participants following data collection outlining the aims and objectives of the project, alongside a **Privacy Notice** stating how anonymity will be protected, and how information will be used. A contact name and telephone number / email address should be provided for queries, and participants should be given the option to have their data withdrawn from the study. For further guidance on covert observation studies, colleagues and students should refer to the Code of Ethics and Conduct published by the British Psychology Society (BPS).

5. RECORDING EVIDENCE AND RECORD-KEEPING

For audit purposes, the University recommends that all project documentation should be stored securely for a period of 10 years. If the project is externally funded, further guidance on document retention may be included in the grant terms and conditions. Students and colleagues who leave the University during this period should ensure that any documentation relating to high-risk projects is retained within their School or Institute. Examples of key documents include:

- Confirmation of ethical approval
- The final version of the approved protocol
- Other supporting documents (e.g. Participant Information Sheet, template Consent Form, Privacy Notice, Debriefing Note)
- A list of participants recruited to the study
- Corresponding evidence of consent

All University colleagues should complete the mandatory e-learning module on the UK General Data Protection Regulation (GDPR), which can be accessed via the Learning Management System (staff login required).

6. UNIVERSITY EXPECTATIONS

6.1 University policy

The University expects all researchers working with human participants to consider the dignity, rights and wellbeing of participants involved in the study, and ensure that an appropriate form of consent is collected and fully documented. All research projects involving working with human participants require approval from an appropriate Ethics Committee. It is the researcher's responsibility to ensure that ethical approval is in place before work commences and maintain a record of key documents.

For more information on University expectations in relation to research activities please refer to the following documents:
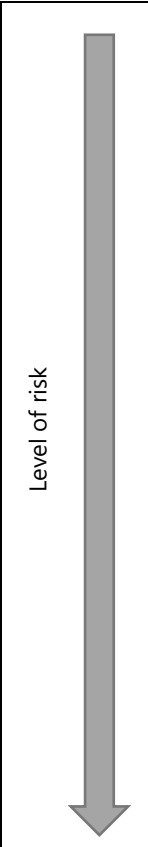
- Code of Good Practice in Research
- Ethics Policy for Research, Teaching and Consultancy
- Research Data Management and Code of Practice

Although formal ethical approval is not required for impact and engagement activities, advice on best practice may be sought from the relevant Faculty Ethics Committee.

6.2 Different approaches to capturing consent

As the University undertakes research in a wide range of subject disciplines, a "one size fits all" approach is not possible. Colleagues and students should therefore adopt an **appropriate and**

proportionate approach to capturing consent based on professional guidelines, legal and regulatory frameworks that apply to their work. The level of risk to participants should also be considered. As a general rule, more robust measures should be put in place where the risks to participants are greater. For example:

Level of risk		
	Basic questionnaire - in which no personal information (such as names or email addresses) is collected.	*Information – provided in a short paragraph at the start of the survey.* *Consent - implied by the participant choosing to complete the survey.*
	Online interviews – to collect more detailed information on participants' opinions / experiences. Conducted online with a range of participants based in different countries.	*Information – provided in an email prior to the interview.* *Consent - consent provided by email prior to the interview. Alternatively, understanding could be checked before starting the interview and verbal consent captured via video recording.*
	Focus groups – group discussion of a sensitive topic conducted in person.	*Information – provided in a written Participant Information Sheet.* *Consent - meeting held with the participant to check their understanding prior to signing a written Consent Form.*
	Invasive procedures – collection of blood samples on campus from healthy volunteers.	*Information – provided in a written Participant Information Sheet.* *Consent - meeting held with the participant to check their understanding prior to signing a written Consent Form. A Witness may also be asked to countersign the Consent Form.*

The University will generally accept different methods for obtaining informed consent as long as it is appropriate to the type of study. This should be considered during the **project proposal stage**, as part of the research design and methodology. If in any doubt, students should seek advice from their Supervisor or Module Leader. University colleagues can obtain advice from their local Faculty Ethics Committee prior to submitting an ethics application. Ethics Committees will also provide feedback to applicants as part of the ethical review process.

7. FURTHER INFORMATION

7.1 Online ethics toolkit

Further guidance on working with human participants is available to view on the University's online ethics toolkit.

7.2 Templates and examples

a) An example Participant Information Sheet (PIS) and template Consent Form are available to view and download from the University's online ethics toolkit. These should be adapted to fit the research project.

b) Academic units may choose to develop their own template forms for different subject disciplines, subject to approval by the relevant Faculty Ethics Committee. Check with your Supervisor or local Research Team whether any templates are available.

c) University colleagues and students can also access examples and template forms developed by the Health Research Authority (HRA).

7.3 Online training materials

Please refer to the training, tools and resources section of the University's Research Governance webpage for links to the following online resources:

a) Research Integrity e-learning programme: the University provides free access to colleagues and students to an online programme on Research Integrity. The programme includes a supplementary module on *'research involving human participants'*.

b) Informed Consent video: training video produced by the Newcastle Joint Research Office outlining the principles of informed consent. This video provides a brief overview of the essential criteria required to correctly undertake the process of informed consent and ensure that it is fully documented.

c) Introduction to working with human tissue: the University has developed an e-learning module which provides a comprehensive overview of the Human Tissue Act and advice for researchers working with human tissue at Newcastle University.

d) External e-learning programmes: online training materials which cover the principles the informed consent are available through Health Research Authority (HRA) and Medical Research Council (MRC).

7.4 Qualitative research methods

In addition to the research skills training provided through the University's educational programmes, colleagues and students can access information about qualitative research methods via the Methods Hub.

7.5 Professional guidelines

A number of professional bodies and learned societies have also produced their own good practice guidelines. Including (but not limited to):

- Academy of Management (AoM)
- Association of Internet Researchers (AoIR)
- British Educational Research Association (BERA)
- British Psychological Society (BPS)
- British Sociological Association (BSA)
- Oral History Society (OHS)
- Social Policy Association (SPA)
- Social Research Association (SRA)

7.6 Ethics Committees

Faculty Ethics Committees can offer advice to applicants on developing an ethics application and supporting documents:

- Faculty of Humanities and Social Sciences – email: HaSS.Ethics@ncl.ac.uk
- Faculty of Medical Sciences – email: fmsethics@ncl.ac.uk
- Faculty of Science, Agriculture and Engineering – email: sage.ethics@ncl.ac.uk

General questions regarding University policy and procedure can also be directed to the Research Strategy and Development service – email: res.policy@ncl.ac.uk.