TASO Transforming Access and Student Outcomes in Higher Education

# Research Ethics Guidance

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# A. HOW TO USE THIS GUIDANCE

This document draws on a range of the available research ethics guidance (see Appendix 2 for examples) and the UK Research Integrity Concordat. Its purpose, however, differs slightly in that it is intended to be a set of practical guidelines and principles that:

**(a)** enable researchers and evaluators of widening participation (WP) and student success to think ethically and navigate the ethics of their work.

**(b)** inform researchers and evaluators in Higher Education Providers (HEPs) in their interactions with their own Research Ethics Committees (RECs) and help them to navigate the complexities of ethically acceptable research/evaluation.

Ethical considerations tell us what we ought and ought not to do. This guidance takes a practical approach, offering advice on the kinds of research/evaluation approaches that the research community considers ethically acceptable. We outline a standard approach to ethical scrutiny (Section C), and also set out the kinds of judgements that researchers/evaluators need to make in order to think and act ethically where they need to go beyond this standard approach (Sections D – L). The final sections of this guidance discuss studies with experimental designs (Sections M – O).

It is worth saying at the outset that ethical scrutiny is not intended to stop good research/evaluation, but it is intended to:

- Protect the human rights of participants in research/evaluation
- Ensure that risks are considered and mitigated and that harms do not disproportionately fall on one social group
- Maintain society's confidence in the ethical self-regulation of the field
- Protect practitioners from claims of unethical behaviour

We hope it is clear that ethics *cannot be subordinated* to researcher/evaluator convenience nor to the additional costs and resources that ethical research/evaluation might incur.

We have laid out clearly what researchers/evaluators need to do to conduct ethical studies. However, it is rarely possible to devise rules that are effective and appropriate in every case. For this reason, we have also identified key principles and ways of thinking ethically that are regularly used to keep researchers/evaluators on the right track. The more complex the research, the more likely it is that the ethical judgements will also be complex. The guidance includes illustrative examples both in this document and the associated case study document. These examples have been simplified and anonymised to draw attention to the key ethical issues. They are not intended to disseminate the findings of actual studies.

This document also contains links to external websites and documents. These are not endorsed by TASO but may support researchers/evaluators in thinking about ethical issues.

Throughout this document, we are concerned with ethics rather than **data protection legislation** on the use of participants' data. Such legislation changes over time, and updated guidance can be obtained from the Information Commissioner's Office. The University of Aberdeen's checklist may also be useful as an example of a checklist, although it should not be relied upon as definitive.

### A note on language

This guidance has been written in an accessible form with illustrative examples to clarify many of the core points. It also uses language, familiar within ethics and research ethics, in particular, that may well be helpful in conversations with RECs and similar bodies. For example, the guidance:

- Uses terms such as autonomy, beneficence, etc. that are important for considering the ethical issues emerging from research/valuation studies.
- Uses the terms 'research' and 'evaluation' as different types of systematic inquiry that share similar methodologies and, as a result, raise similar ethical issues.
- Clarifies the use of terms common in practice but ethically unhelpful, such as 'opt-out consent', which is conceptually problematic and not a reliable form of consent.
- Clarifies the distinction between terms that are often used interchangeably but have different ethical implications, such as the distinction between 'incentives' and 'compensation' (see Section G. 1).

## B. ETHICS AND RESEARCH

While this document shares much in common with other ethics guidance, it has been written specifically for those working towards WP in higher education and supporting the success of students from diverse backgrounds. In developing this guidance, it has been important to be conscious of the following key features of WP and student success work:

- **The work is underpinned by a series of values and commitments to supporting young people** to 'take charge of their destinies' and 'pursue their educational and career aspirations'. Significantly, it places the student and their wellbeing at the heart of the process. These values are shared by the research ethics guidance contained here. Students and their data are to be treated with respect throughout the research and evaluation process.
- **There is an ongoing need for rigorous research and evaluation of projects.** A range of qualitative and quantitative methods are needed to improve WP and student success projects. Whilst the process of conducting ethical research – sometimes requiring review by an ethics committee – can seem daunting, this guidance is intended to minimise barriers to conducting the necessary evaluations and research.
- **An inclusive approach is important.** Students should feel that their voices can contribute to research and evaluation without worrying about what their involvement will mean for them or their data. We should take account of students' specific characteristics or needs, their anxieties, and any negative prior experiences of research and evaluation.

This research ethics guidance has been written to support these underpinning values and ensure that WP and student success teams can conduct the rigorous evaluation and research they think necessary, as well as that required by statutory and funding obligations.

Whilst WP practitioners tend to use the term 'service evaluation/evaluation' to cover a range of studies, the terms 'audit' and 'research' are regularly used in research ethics (following medical research ethics practice). Audit refers to those studies that need a lower level of ethical scrutiny than research. Thus, some evaluations are audits and others research. While there are no generally agreed criteria of what constitutes an audit and what is considered research, the table below provides a guide.

| Audit | Research |
|---|---|
| Never involves experiments[1] on human subjects | May involve experiments on human subjects |
| Is a systematic approach to the peer review of educational support to identify opportunities for improvement and to provide a mechanism for bringing them about | Is a systematic investigation that aims to increase the sum of knowledge |
| Never involves allocating people randomly to different treatment groups | May involve allocating people randomly to different treatment groups |
| Never involves a completely new intervention | May involve a completely new intervention |
| Never involves disturbance to the participants beyond that required for normal educational activity | May involve extra disturbance or work beyond that required for normal educational activity |
| May involve students/pupils with the same educational need being given different interventions, but only after full discussion of the known advantages and disadvantages of each approach. The student/pupils can choose freely which intervention they receive | May involve the application of strict selection criteria to students/pupils with the same educational need before they are entered into the research study |
| Measures against a standard set of expectations to address educational needs | Usually involves an attempt to test a hypothesis |
| Is used to inform internal policy and practice with limited circulation to those involved in the activities | Is intended to be communicated to a broad audience beyond the individuals and institutions directly involved |

Adapted from GAIN. See also Defining Research

## Example 1

You want to know that your transition support programme for first-year students does in fact enable them to understand the requirements of undergraduate assessment and marking criteria. Students have two reviews each semester with their academic adviser and you add in some specific questions on their understanding of marking criteria. These questions are asked both of students on your transition programme and other students on the same courses. The answers to these questions are then reviewed by the team across all students involved and also contribute to the academic advisors' reviews.

This would seem to be audit

Where a study meets all the criteria for an audit, it is usually not necessary to gain full (formal) ethical approval – although different HEPs and organisations have different procedures for recording this.

Identifying a study as research requires more detailed scrutiny and a formal process of ethical review in some organisations. Some will be low risk and follow a standard process of anonymisation and gaining informed consent from participants; others will involve a higher-risk to participants, require greater effort from them, or need to deviate from the standard process of gaining informed consent.

## Example 2

Taking the example above, if, however, you were testing out different sets of questions with different students (by allocating students to one of two groups) or had changed the way you taught marking criteria to see if it was better than what you usually did, then it would no longer be audit but research.

[1] That is, an intervention where we have a very limited idea of possible impacts, conducted in order to gain more knowledge about that intervention.

# C. LOW RISK STUDIES EMPLOYING ANONYMISATION AND FOLLOWING THE STANDARD PROCESS OF INFORMED CONSENT

**This section:**

- **Does not assume detailed knowledge of research ethics**
- **Offers a simple 'standard' approach to conducting low risk, ethical research/evaluation**
- **Identifies the characteristics of low risk research/evaluation**

The process for applying non-standard approaches to research/evaluation will be covered in Section D and subsequent sections.

## Example

We can amend the example above, regarding students' understanding of marking criteria, to make it a *very low-risk study*. Testing different sets of questions where we have no reason to believe one set is obviously more helpful than the other would be low risk. *A higher but still low risk study* would change the way you taught about marking criteria where there is a non-negligible risk of potential harm (for example, students may understand less), but as long as the change is offered to all students and is thought by staff to have potential benefits, this would again be low risk.

Alternatively, the ethical issue may not concern the conduct of the study, but its dissemination (see Section M on ethical issues in dissemination). Many ethics issues can be resolved by anonymising data appropriately and following a standard process of gaining informed consent.

1. *Low risk of harm, physical, emotional, psychological, or educational, to participants* (see Section D for a discussion of risk)

   Assessing risk is a judgement rather than a calculation. Consider what might go wrong in a study for participants and how likely that negative event is. If, for example, we were studying a new way of supporting pupils in considering applying to a HEP (low risk of direct harm), using a tried and tested approach (low likelihood of any negative effects), then this would have *low risk* to the pupils, and evaluation may help improve the approach. Using a novel approach (higher likelihood of a negative effect) would make this a higher-risk research/evaluation study.

2. *Participants are fully informed about the study* (see Appendix 4 – PIS)

   The study uses a proforma that ensures all significant information about the study is communicated to participants. Using an appropriate proforma ensures that nothing is missed.

3. *Participants are asked for their free and explicit consent to be involved and this is recorded* (see Appendix 4 – PIS)

   Having been informed of the study, participants record their consent to be involved and in doing so recognise the requirements of the study. (**Note:** This differs from consent as a lawful basis for processing personal data under data protection legislation, and should be thought of as separate).

4. *Parental consent is obtained for under 16/18-year-olds*

   There is no definitive point at which parental consent is considered best practice. Adults (18+) do not require parental consent and, in most circumstances, 16–18-year-olds are also thought able to give consent without parental consent being sought. Normally, parental consent will be sought for participants under 16.

5. *Anonymisation/pseudonymisation*

   All identifiable information should be removed from the data (i.e. data anonymised) as early in the process as possible (see ICO guide on Anonymisation and subsequent guide on How to Ensure Anonymisation is Effective). The lowest risk is to anonymise at the point of data collection (e.g. an anonymous questionnaire). Where necessary, a researcher/evaluator may keep the data confidential rather than anonymised for a period (i.e. pseudonymise the data). This can be achieved securely using a deanonymising key (usually a document that links identification numbers in the data to people's real names). The key must be kept securely, electronically encrypted and away from the data collected. Recital 26 of the UK GDPR makes it clear that "personal data which have undergone pseudonymisation, which could be attributed to a natural person by the use of additional information should be considered to be information on an identifiable natural person".

Where these five conditions apply, the research/evaluation study will in most circumstances be ethical. However, there are numerous ways in which ethical issues can emerge in a study, and these need to be predicted, and responded to, by researchers/evaluators.

More information on all these issues can be found in the sections of this guide indicated below:

- Assessment of harm
  - Section K. Using students/pupils as co-researchers
- Informed consent
  - Section E. Participants' consent
- Parental consent
  - Section G.2. The age(s) of consent
- Anonymising/pseudonymising data
  - Section J. Anonymity and confidentiality

While this process covers ethical consent, a parallel process of ensuring compliance with data protection legislation is equally important. We cannot advocate for any one party's data protection guidance and advise evaluators/researchers to consult a Data Protection Officer or suitably qualified data protection professional for each project. One example of a useful checklist can be found in the University of Aberdeen's Data Protection Guidance[2].

## D. THE UNDERPINNING PRINCIPLES OF GOOD RESEARCH ETHICS

**This section:**

- **Outlines key principles and ideas in research ethics.**

It is worth noting that research ethics derive from two different histories. The first is the international horror felt at crimes committed against human beings in the name of research from 1939 to 1946 (leading to the 1964 Declaration of Helsinki). The second is the need for professionals in positions of power to be seen to be acting in the interests of those over whom they have that power. This second strand has given rise to a range of 'professional codes of conduct', intended to maintain social confidence in the professions. Research/evaluation needs to be both ethically justifiable *and* socially acceptable. A study can be ethically justifiable yet at the same time socially unacceptable – ethical scrutiny needs to be concerned with both aspects.

Given that social attitudes change, and what is considered socially acceptable also changes, this guidance focuses on 'ethical justification'. In reading it, however, researchers/evaluators should also consider whether their study – however valuable – may be seen as socially unacceptable.

[2] Note that TASO does not endorse any external guidance identified in this document.

## The principles of research ethics

Research ethics are grounded in two accounts of how we relate to other people (and often other sentient beings). The first concerns individual rights, and the second the weighing of risks involved in an activity. Whereas national law enshrines *what all people must do* (e.g. Data Protection laws), ethics set out broad, but rarely unanimously agreed, principles. Thus, research ethics are not primarily focused on following a set of rules – although standard ways of acting have been developed – but on making good ethical judgements.

In Section C, we looked at a straightforward, ethically justifiable way to conduct research, using a regularly used and well-developed process. Very often, studies require a different approach because of issues such as increased risk, difficulties in gaining full consent or the use of institutional-level data. When researchers design such studies, extra care and vigilance is required, including ethical reflection by the researchers/evaluators and, often, ethical scrutiny by those not directly involved in the study.

While it is unacceptable to undermine a person's individual rights, there are differences in opinion on individuals' rights and what these mean for researchers when conducting research/evaluation. Various codes have been developed to state explicitly the kinds of rights people ought to have. Some are high level (e.g. Universal Declaration on Human Rights), while others set out individuals' rights in relation to research/evaluation. For example, the British Educational Research Association has a code of ethics that its members are expected to follow (see Appendix for links to a range of other research ethics guidance).

However, even when there is agreement on an individual's rights, it remains a matter of judgement as to how those rights should be respected in practice. Critically, ethical scrutiny should involve the judgement of a well-meaning person with a good understanding of research/evaluation and ethical thinking, who is able to reflect on a proposed research/evaluation study. Put simply, those conducting ethical reflection/scrutiny must have the right knowledge and experience in research/evaluation and ethics and must intend to protect an individual's rights rather than seek ways to 'get around' the regulations.

The second account is concerned with risk, the level of potential harm or benefit that a study may produce and who experiences this benefit or harm.

## What might count as a harm?

Harms may be physical, mental, emotional or educational (although this list is not exhaustive). In educational research/evaluation, physical risks can usually be considered as part of normal health and safety processes. We do not, for example, invite participations into unsafe buildings or unsafe areas of a city, and we should consider any possible physical harm they may face from other participants involved in the study.

Increased stress or significant emotional discomfort are perhaps more likely difficulties in educational work – including asking participants to revisit difficult periods in their schooling or family life. Even reminding them of their WP status risks evoking a sense of 'not belonging' in higher education.

Educational harms can be more subtle. These may result from directing a student or pupil away from their studies to be involved in the study, or trialling a new intervention with no real idea of its precise impact and therefore not being able to plan suitable 'next steps' for participants.

Most studies have the potential for unintended consequences that are not positive for the participants. For example, a study on family context may increase alienation from the participant's family.

As with individual rights, the assessment of potential benefits, harms and their distribution requires *judgement*, again, the judgement of a well-meaning person competent and able to think through such matters. In general, an assessment should consider the following questions:

- Do the potential benefits outweigh the potential harms?
- Is the level of potential benefit worth risking the potential harms?

- Is any single person or group likely to suffer a disproportionate level of harm?
- Has everything been done to mitigate the potential harms?

We may, therefore, judge that a low risk study with low potential harm should go ahead, even if the benefits are relatively small. However, in a higher-risk study with higher potential harm, we would want the potential benefits not only to exceed the potential harms, but to exceed them substantially. There may also be cases in which the absolute level of harm or risk is so great that the study should not go ahead, even if it promises to produce very substantial benefits which outweigh even the significant harms. We should also pay close attention to the ways in which harms and benefits potentially accrue to different groups of individuals and be prepared to take remedial action where the mismatch is too marked. For example, excessive research/evaluation of a limited group of WP students increases the costs to them, risks labelling and potentially distracts them from their course of study. A risk/harm assessment table helps identify and track risk (see the University of Essex guide).

When thinking about research ethics, therefore, the researcher/evaluator should:

- Consider the individual rights of potential participants
- Consider the potential benefits, harms and the distribution of those harms

The expectations and rules for ethical conduct follow from these two basic principles

These two central areas of concern have in the past been articulated in the form of four basic areas of concern which, together, form a framework for thinking ethically about research and evaluation: beneficence, non-maleficence, justice, and respect for autonomy.

## Beneficence

This is the principle of doing good where possible. In research, it requires that: (1) the proposed research should do at least some good, and (2) if the proposed research also involves unavoidable burdens and harms, it should deliver a significant positive balance of benefits over harms. The assessment of costs and benefits is not an exact science, but researchers/evaluators should be able to think through and justify their research/evaluation in such terms.

## Non-maleficence

This is the principle that the absolute level of burden or harm should not be excessive, for example, the possibility of permanent and irreparable damage to the educational prospects of one or more individuals, even if the knowledge gained promises to bring great benefits. The principle of non-maleficence must be considered separately from the principle of beneficence because it imposes a hard limit on the burdens or harms that can be traded off against promised benefits. A research/evaluation project will not be ethically acceptable if the level of burden/harm involved exceeds reasonable limits.

## Justice

This is the principle that the burden/harms and the benefits of research should be equitably distributed among affected groups. No group should be asked to bear excessive burdens for the sake of benefits to which they will not have proportionate access. For example, we do not want to overburden students from marginalised communities, or over-burden current students who will not benefit from the research/evaluation if any benefits will only be experienced by future students. Such disparities should be avoided as far as possible, and no group should be expected to consistently bear burdens for the benefit of others.

### Respect for autonomy

This principle focuses on the right of research participants to exercise reasonable control over what is done to them. The principle of respect for autonomy gives rise to strong practical requirements, such as the expectation that the informed consent of research participants will be obtained wherever feasible.

## E. PARTICIPANTS' CONSENT

**This section:**

- **Explores whether consent is necessary and**
- **How to gain informed consent**

Consent is often needed for studies involving human participants, although not always. There are four possible ways for a researcher/evaluator to address the issue of consent in different types of study.

NOTE: As mentioned earlier, consent for participation is not the same as consent on a legal data protection basis and must be approached as separate and different. Data protection legislative requirements for consent are not referenced below.

### *Is the consent of participants necessary?*

While the presumption ought to be that consent may well be necessary, there are several situations in which consent is not necessary. Examples include:

- Observation in public spaces (see Section L)
- Anonymous tracking of everyday activities (e.g. the number of research-methods textbooks issued by the library to first-year students)
- Use of aggregated data of a cohort of pupils

In some situations, consent is *not* needed for a particular study because **prior consent** has been obtained from participants. For example, students may be asked to give consent for their assessment and demographic data to be used for research/evaluation at enrolment. As a result, a specific study using this data does not need to ask for consent.

Even where consent is not needed, researchers/evaluators may decide to give the participants the option to either:

- Positively choose to be part of the study, that is give their 'assent'
- Remove themselves from that study, that is 'opt out of the study'

**Consent is required** where participants are required to engage in activities that they would not normally do. These include:

- Completing a research instrument: questionnaire, interview or focus group
- Engaging in a workshop or learning activity specifically for the study
- Being observed in non-public settings or private activities
- Use of their data containing personally-identifying information

Where consent is needed, it is normally expected that participants will be informed about the study in enough detail to make an *informed decision* as to whether they want to consent or not. On occasions where the methodological design of a study requires participants not to know the precise reason of the research, participants may be given partial information.

# IS ETHICAL CONSENT NEEDED FOR THIS SPECIFIC STUDY?

## YES

Does the design of the study preclude – for methodological and NOT merely practical reasons – obtaining fully informed consent in advance?

### NO

Can consent be satisfactorily managed in a "light touch" way e.g. the act of submitting an anonymous online questionnaire?

#### NO

Fully informed consent required

#### YES

### YES

Proceed, with caution, to obtain partially informed consent, putting arrangements in place to ensure that participants are fully informed at the first practicable opportunity, and where possible provided with an opportunity to remove their data from the study if they so wish.

#### YES

## NO

Proceed, conditional on obtaining the relevant institutional permissions to access data

Has prior generic consent has been given e.g. during student enrolment?

Have you confirmed that consent not needed e.g. occurring in a public space?

Proceed, noting explicitly that consent is not required or that prior consent has been obtained

Are there reasons for telling subjects about the study anyway and allow them to request that their data not be used e.g. reputational risk of to maintain ongoing good will?

### YES

Either participants are asked to assent or opt-out of the study

### NO

## 1. NO CONSENT NEEDED FOR THIS STUDY

### Examples where no study-specific consent is needed:

*No consent needed:* if you have designed a study that sends one of three different formats of letters (with the same content) to parents of WP students to see whether this makes any difference to parents' attendance at WP events. Parents are randomly allocated either letter A, B or C and the number of parents from each group attending a series of public events is recorded. There is no need here for consent as there is nothing to consent to. The HEP has the freedom to send letters to parents in any format it sees fit and parents do not need to consent to a particular format. The attendance data is both anonymous and a record of a public event.

*Prior consent:* if you are conducting a study of HEP students *and* the enrolment forms of the HEP ask students for consent to use their data in research/evaluation studies, then conducting a study in line with the consent given does not require further consent. It needs to be emphasised that prior consent is full consent; it is not necessary to go back to participants for every new study.

There are several situations where consent is not required, although it is important to check that this is indeed the case. For example, you need to check what students agreed to be involved in when signing their enrolment form. It could be argued that your study would not have been envisaged by students when they signed the form and, therefore, students were not *sufficiently informed*.

In the above example, parents of WP students were not asked for consent because the attendance data was collected as part of a public gathering. The claim that an activity is public is a frequent reason for not requiring consent. It is not always clear, however, whether an activity is a public activity or not (see Section L). Further, the allocation of letters is also clearly a matter for the HEP (within reason, they can do what they want in communicating with parents) and thus the allocation to different groups is not experimental, where the fundamental content of the letters is the same.

In some cases, there may be other reasons to inform participants about the study because of what is seen as socially acceptable. These reasons may include very pragmatic concerns to ensure that the study team maintains good relationships with other stakeholders (students, parents, etc.). A study team may inform those whose data they are gathering and offer them the opportunity not to have that data used; that is, the opportunity to '**opt out**'[3]. Alternatively, a team may decide that although they do not need consent, they nevertheless want individuals to actively agree to have their data used; that is, participants are asked to '**assent**'.

## 2. WHEN CONSENT IS GIVEN ON PARTIAL INFORMATION

There may be occasions where the study's design requires participants not to know its precise purpose. Such research/evaluation requires careful ethical scrutiny as it undermines participants' autonomy. Consent given on partial information may be legitimate where the study promises significant benefits and there is no other way that it can be carried out. However, such situations are the exception.

### Examples:

A study is designed to investigate the ways in which class prejudice is expressed in informal conversations between students at an elite university. The research/evaluation team know that students can self-police their language during seminars, and covert bugging of student halls of residence has been deemed too invasive by the university concerned.

[3] Individuals are not being asked for 'opt-out consent' but invited to opt-out of a study where their consent is not needed.

The research/evaluation team design a study in which participants are recruited to a study involving mathematics puzzles. Participants attempt two short mathematics puzzle tasks interspersed with a long period together in a lounge area with free refreshments. Participants are told that all the rooms have microphones due to the study design.

The researchers/evaluators are not interested in the mathematics puzzles but in the conversation in the lounge. The study involves deception in that the information given to participants is intended to misdirect their attention, although they have been informed of and consented to their talk being audio recorded.

Where only partial information is given, researchers/evaluators should ensure that:

1. Participants are not being deceived into doing what they would reasonably find offensive if they had been fully informed
2. Participants are given the maximum information possible, within the constraints of the methodological design
3. Participants are fully debriefed and, if necessary, supported after the data collection has occurred
4. If possible, participants who do object after being debriefed have the option to withdraw their data from the study

*Fully covert research* without a full debriefing is rarely considered ethical. Studies of this type are usually limited to researching violent and extremist groups (e.g. work on Glasgow Gangs or the English Defence League). In such cases, the unusual nature of the research may justify an exceptional approach to withholding information from participants or deceiving those participants.

## F. PRINCIPLES AND PRACTICES OF GAINING FREE, INFORMED CONSENT

**This section:**

- **Identifies and explores the principles of informed consent**
- **Sets out good practices for researchers/evaluators in informing potential participants and recording their consent**

Section C set out a simple approach to gaining informed consent for studies that carry a low risk of harm to participants. This section gives a more detailed account of the principles of informed consent and addresses specific issues that raise concerns during ethical scrutiny.

### 1. INFORMING PARTICIPANTS

Where informed consent is ethically necessary for a project, the researcher/evaluator needs to ensure that participants are fully informed. This is not simply a matter of supplying them with information; the information must be supplied in a form that enables participants to make a truly *informed decision*.

The information is usually presented as a written information sheet (see the example Appendix 4 – PIS) in a readable and easily understood format. The necessary information covers:

- The goals of the research/evaluation – why is it being carried out and what does it aim to achieve?
- The basic mechanics/methods of the research – how will the above aims be achieved? And what, therefore, will happen to the participant if they agree to participate? Are there any associated risks for them?
- What will be done with the results of the research/evaluation – for example, how will the data be stored and where and when will the results be published?

- Will participants have an opportunity to reconsider or withdraw from the research/evaluation once it is under way? Will it be possible to withdraw their data, and at what point will this no longer be possible?
- Whom should participants contact if they require more information, or wish to withdraw or raise any concerns about the research/evaluation?

None of the above requires the researchers/evaluators to indulge in lengthy and potentially inaccessible discussions of the academic background, study design and methodology. The focus is on what participants need to know to make a fully informed decision.

All the above information must be available in a suitably accessible format, bearing in mind the educational and language backgrounds of potential participants and their potential disabilities. An increasingly popular way to inform potential participants is using video, although – as with written documents – any video must be accessible, e.g. by using captions.

## 2. ENSURING PARTICIPANTS ARE *FREELY* CONSENTING

Having informed potential participants, a second concern is whether they are able to give their consent *freely*. We will deal with the specific issue of incentives in Section G.1; however, the more common issue is that research/evaluation is often conducted with people with whom we have a prior relationship.

### Examples:

A study is evaluating students on a Student Success scheme you are running. In such cases, the students may feel pressure to participate because of their relationship with you (or your organisation). They may fear that not participating in the evaluation will cause problems for their involvement in the scheme or, conversely, that participation will give them access to extra benefits on the scheme.

In such a situation, consent may be given but not freely. Unless a study team can address such potential pressure, ethical scrutiny may well consider the study unethical.

There are two ways to mitigate such potential effects:

1. Be clear in the information sheet that there are no additional advantages to those who participate in the research/evaluation. For example, everyone gets the same level of care, and participants can withdraw (see Section F.4) from the programme with no detrimental consequences for them. Often participants are reminded during the study that '*any* help is gratefully received' to offer reassurance that their participation is a help to the researchers rather than a requirement.
2. Identify a 'gatekeeper' who is charged with making the first contact with potential participants and supporting them to decide whether they want to take part. The gatekeeper is not a researcher/evaluator and provides 'distance' between potential participants and those conducting the study.

Even with these approaches, there is an ongoing requirement for the researcher/evaluator to be sensitive to participants' feelings or to any signs of unease arising from participation.

More generally, researchers/evaluators should minimise possible *coercion* effects. In the example above, the coercion is internal, i.e. it is generated by the potential participants. They come to believe certain things that are not true (i.e. they believe, erroneously, that participation will be in their self-interest). This is a regular difficulty in conducting studies and the researcher/evaluator has an ethical duty to take responsibility for mitigating its effects. Other forms of coercion are external, generated by features of the study itself; these include the use of incentives (see Section G.1) and, potentially, the use of peer co-researchers (see Section K.3).

As well as ensuring that participants are fully informed, researchers/evaluators need to ensure that participants are free to act on the information they have, by minimising possible sources of coercion.

## 3. TAKING AND RECORDING CONSENT

As we noted above, there are occasions where participants' consent is not necessary. However, where consent is ethically required the participant should make a positive decision to be involved – that is, 'opt-in consent' – and that decision should be formally recorded.

Consent ought to be recorded at the outset of the research or evaluation. Initial consent can be 'light touch', as in the case of questionnaires (see below). In the case of interviews and focus groups, it is usually recorded formally (see consent form Appendix 5 – Consent) in a way that requires the individual to show that they understand the various elements of the study.

Where a study takes place over a long period and has several points at which data is collected, ongoing consent is usually requested verbally and recorded as part of the researcher's/evaluator's notes. This is a reminder to participants that they have consented but that they have the right to withdraw. Alongside the reminder of their right to withdraw, participants should be reminded of how to do so.

Light touch initial consent can be used for methods such as questionnaires. For an online questionnaire, it can be assumed that the individual is consenting to take part if they press the 'submit' button. The same may be true of an evaluation of a large public engagement event where participants are given an evaluation sheet to complete on their own. Again, submitting the sheet can be considered as consent to be involved. However, in all such cases, the questionnaire should include information about the study and how the data will be used, and clarify that its submission will be regarded as indicating consent to participate without any right to withdraw.

## 4. THE RIGHT TO WITHDRAW

Even after giving informed consent, participants retain the right to withdraw from the study or not answer specific questions. They ought to be informed of this right in the information sheet provided together with how to withdraw and what will happen to any data collected up to that point. The process for withdrawal should be as simple as possible, e.g. emailing or telling a member of the study team. There should be a way of recording the participant's withdrawal so that all relevant members of the study team know of it.

Some studies will allow participants to withdraw all the data collected in the study and permanently delete and destroy the data they have. Others will retain data already collected but not collect any more. The decision is practical rather than ethical, so long as participants have been clearly informed about what will happen before the study begins (keeping participants informed is also a data protection legislative requirement).

If there is a point after which a participant will not be able to withdraw data, then this ought to be clear in the information initially provided (e.g. where data will be anonymised or aggregated), giving a clear date, for example, 'two weeks after the interview', 'before the end of February 2028'. Such information should avoid moveable cut-off times such as 'before the data is analysed' as participants will not know what date this will be.

Some research designs, such as anonymous questionnaires or focus groups, make the withdrawal of an individual's data difficult or impossible. In such cases, the information given ought to make this clear. For example, an anonymous questionnaire should state, 'submitting this questionnaire shows that you are consenting to us using your data. It will not be possible to withdraw your data after you have submitted it'. This transparency remains a requirement of data protection legislation in the UK and EU

# G. SOME ADDITIONAL ISSUES IN CONSIDERING CONSENT

**This section:**

- **Identifies and discusses specific issues related to the need to ensure 'freely given consent'**
- **Distinguishes between payments that support participants to do what they think they should do (expenses and compensation) from those payments that coerce them (incentives)**

## 1. THE USE OF COMPENSATION, INCENTIVES AND EXPENSES

Participants[4] in a study may be offered money or gifts as part of their involvement. These fall into three categories:

1. **Expenses** to cover the extra costs of being part of the study. They may include the costs of travel or a subsistence allowance for participants to attend at a specific location. Any expenses provided must be in line with the additional costs that the participant has incurred. It would, for example, be inappropriate to offer a student a £50 voucher at the university café on the grounds that this was for lunch, but legitimate to offer pizza and a drink as part of a focus group.
2. **Compensation** may be offered in the form of a small gift in recognition of the time and effort involved. The participant is already inclined to be involved, i.e. they do not think participating is against their best interests, but has not got around to actually 'signing up'. Often, such compensation is in the form of a voucher, perhaps a book or music token. Other compensation processes may, for example, include participants in a prize draw or give a small donation to a charity for every questionnaire completed. Any compensation offered should be merely a small 'thank you' from the research team; any more may coerce the participant to consent to their involvement.

Expenses and compensation arrangements are a standard element in research/evaluation and are often seen as commendable in recognising the importance of the participants' contribution. There is however a third possibility – incentivisation.

3. **An incentive** is any gift or payment that may coerce a person to participate in a research/evaluation study. There are good methodological reasons to be suspicious of the effect of incentives on the validity of study findings. However, there are also ethical issues in that such incentives are intended to override an individual's desire not to give consent, and/or to take part in a potentially harmful study. Research/evaluation studies ought to avoid the risk of incentivising potential participants, a matter which involves careful consideration of any compensation offered.

## 2. THE AGE(S) OF CONSENT

There is no universal agreement on the age at which an individual can consent on their own behalf to be involved in a study and when it is necessary to gain the consent of an appropriate adult (usually their parent/guardian). Some institutions and groups use a 'hard' and generally accepted point of age – either 16 or 18 depending on the nature of the study. However, the principle of autonomy also allows individuals to make decisions regardless of age so long as they are competent to do so (this is sometimes referred to as Gillick competency).

The context of the study and what is required must be considered. It may be acceptable to ask a group of young people or even children to complete a short questionnaire after a WP event without seeking formal parental consent, especially where data is given anonymously. Where a study is more formal, where the data collection is more demanding or when data is not collected anonymously, in addition to the young person's consent, the consent of their parent/guardian would usually be sought. Where research/evaluation takes place within an organisation, such as a school, then consent is usually also required from the senior leaders in that organisation.

[4] Expenses/incentives only concern participants. Where we recruit and employ students or pupils as co-researchers to conduct fieldwork for the study, they can receive remuneration for the work they carry out. However, see Section K for a further discussion on the ethical issues involved in deploying peer co-researchers.

Normally, young people's 'assent' or agreement to participate is required regardless of the consent of adults. It is rarely the case that either teacher or parent/guardian consent is sufficient for a young person's involvement in a study.

## 3. THE ROLE OF THE GATEKEEPER-GUARDIAN

The extent of the role of the gatekeeper-guardian is disputed and different reviewers and RECs take different positions on its validity. In most situations, although responsible adults, such as teachers, are able to provide consent on behalf of their institution – e.g. permission for a study to take place in school time – they do not have the right to give individual consent on behalf of pupils.

Some research ethics guidance (e.g. BERA), however, indicates that teachers may, under some (unspecified) circumstances, give consent for pupils' data to be included in a study. The gatekeeper-guardian must hold a position of authority and responsibility with respect to participants, such that they would bear significant responsibility for any harm occurring as a result of the research. However, even in these situations, individual pupils or their parents retain the right not to agree to participate. Further, such arrangements would seem only to be possible where the school is agreeing to allow researchers/evaluators to study pupils engaged in regular classroom activities.

In general, the use of gatekeeper-guardians for consent is an act of last resort to conduct a significant study. There are no sustained arguments for using gatekeeper-guardians in this way for research/evaluation with adults.

# H. CONTEXTUAL INTEGRITY

**This section:**

- **Extends the discussion on informed consent in specific circumstances where consent is difficult to obtain**
- **Discusses the potential, limitations and expectations of contextual integrity in research/evaluation**

Section F sets out standard rules of informed consent that apply to typical research contexts. However, in some contexts – particularly those in which the boundary between public and private behaviour or information is not clear (see Section L), or the boundary between research and audit is not clear – it may be possible to ethically justify such work using *contextual integrity*.

Information flows between people and groups in many ways. Research and evaluation are based on flows of information from participants to researchers/evaluators. Contextual integrity focuses on the different types and levels of consent that are required for different types of information flows, regardless of whether they are for research or evaluation.

For example, Twitter is a one-to-many flow of information. When you tweet, unless you have specified preferences within the settings you have access to, you have no control over who will be able to read it. By way of the contract you enter into with Twitter for using their service, you give permission to people to use that information as they please. An email, on the other hand, has a different set of ethics, depending on the relationship between sender and recipient and the content of the email.

In each case, there are different expectations of how the information should be used and shared. The standard rules of informed consent establish a particular context built on a contract between participant and researcher/evaluator. The contract sets out the specific ways in which the information shared will be used and for what purposes; on the consent form, the participant and researcher/evaluator agree to this contract.

Contextual integrity is useful when dealing with data collection in a public or semi-public data context. Rather than setting the ethical bar as high as a distinct contract between participant and researcher/evaluator (as in the case of the information sheet and consent form), it considers the context within which the information is flowing and asks what is ethically appropriate.

### Example

When observing a WP event, it might be appropriate to announce that you will be observing what is happening as part of the evaluation but reasonable to assume that, in this public or semi-public context, individuals are aware and consent to their behaviour being observed. This is unlikely to be the case in a self-help group meeting where the context implies a higher level of privacy.

Furthermore, consideration must be given to data protection obligations no matter how the data is collected. Whether data is collected directly or indirectly from an individual/data subject, a Data Protection Notice/Data Privacy Notice must be provided at the point of collection. Where this is not possible, it must be made accessible to anyone whose data is collected, and the reason why it cannot be delivered directly to individuals must be explained.

For specific guidance on the use of social media in research/evaluation see the ESRC funded guide.

## I. ENSURING PARTICIPANT WELFARE AND WELLBEING

**This section:**

- **Focuses on the issue of harm and the risk of harm to participants**
- **Identifies questions to be addressed to ensure the wellbeing of participants in research/evaluation**

All research/evaluation brings with it the potential for harm, and such risk is inevitable if studies are to be conducted on human beings. For example, interviewing a WP student about their difficult journey into university and the complexities of finding their feet may cause distress and re-open wounds that had begun to be forgotten. This is not a bar to conducting such a study – such life histories are important to know and understand – but it places particular responsibilities on the researcher/evaluator to mitigate the harms where possible and provide support if necessary to the participant.

### Example

A study is interested in exploring the educational journeys of students into higher education. A narrative unstructured interview design is used. The study team recognise that elements of these interviews may well cause distress and impact negatively on the mental health of some participants.

They assess the risks and their likelihood and reflect on the students likely to be most affected. They implement a three-fold mitigation of harm process. Firstly, they use a pre-interview filter questionnaire to exclude those potential participants whom they think will experience a significant negative impact. Secondly, they identify the potential harm in the information sheet and add some organisations that participants could contact for support. Thirdly, the interviewers are supported to think through the possible negative reactions of participants in the interview and role play how they will respond. At the end of the interview, interviewers will give each participant a sheet identifying appropriate organisations they can turn to for support.

The risk of harm still exists but its impact has been mitigated as a far as possible.

Sometimes, the potential for harm *is not inherent to the study* but caused by its circumstances or contingent features. These may be harms due to the location in which the study takes place – perhaps the physical harm of an accident or psychological harm due to the failure of that location to meet the needs of a participant's disability. These contingent potential harms should be addressed and removed.

The three elements in ensuring participant welfare and wellbeing are: assessing harms, mitigating harms and providing support. The researcher/evaluator has ethical obligations before, during and after the involvement of the participant. This section also addresses the specific issue of safeguarding children and young people.

## 1. BEFORE THEIR INVOLVEMENT

In designing a study, thought should be given to identifying and recording potential harms. Where these harms cannot be removed entirely, the researcher/evaluator must identify what they can do to mitigate them, which harms remain, and how support can be offered to participants (see, for example, University of Essex guidance). This identification of potential harms should include a consideration of the diversity of potential participants, for example, considering whether disability, ethnicity or religious beliefs may affect the potential harms.

Interview participants should be told in the information sheet about any potential harms and how they can protect themselves. For example, they should be told that it is their right not to answer a particular question. This is in addition to their right to withdraw.

### Example

The information sheet may say 'the interviewer will ask questions about your educational journey into higher education. We are aware that this may be an emotional subject for some participants. You can tell the interviewer that you do not want to answer a particular question or that you want to finish the interview altogether. If you do find some of the questions unsettling, then you can discuss the issues with student welfare (please insert email address & telephone number). You can also contact the Student Union helpline on.

If you are distributing a questionnaire, then its introduction should warn potential participants of possibly disturbing topics. Questionnaires should also contain details of how the participant can access support if they have been affected by the questionnaire topics (for example, signposting to support services).

## 2. DURING THEIR INVOLVEMENT (AND PARTICIPANT DEBRIEFING)

Where research/evaluation is happening synchronously (either face to face or online), there is an obligation on the researcher/evaluator to be sensitive to any harms occurring in the process of the study. They can give participants time to collect themselves, remind them that they can refuse to answer a question and perhaps, in some circumstances, terminate the data collection.

At the end of data collection, the researcher/evaluator may direct the participant to possible sources of support, for example, student services within the university, or local charities that offer appropriate support.

In studies where the risk of mental or emotional distress is higher, there may be a need to clarify with the participants the precise purpose of the study, especially where the participants' lack of clarity on the study is causing them difficulties. It may be necessary to build in time to debrief the participant, remind them of their right not to answer questions or to stop the interview, address the immediate effects of their anxiety or distress and offer avenues of support. Such activities need to be carried out sensitively by researchers/evaluators with the appropriate skills and experience. Where the study involves data collection and a researcher is not present (e.g. a questionnaire), then debriefing may take the form of a written summary or video which identifies organisations where the participant can ask for support.

## 3. AFTER THEIR INVOLVEMENT

After a participant's involvement, the researcher/evaluator has further responsibilities in relation to their wellbeing. These can be summarised as follows:

1. Use the data in line with the purposes of the study as agreed by the participant.
2. Ensure that data is anonymised or pseudonymised[5] in line with the participant's expectations.

[5] Anonymised data cannot be attributed to a specific person, whereas pseudonymised data can be so attributed with additional information (e.g. a document which links identity codes in the data with real people).

3. Ensure that the participant's data is used in ways that reflect their espoused views rather than views/ideas that they do not hold, possibly including respondent validation.
4. Ensure that data is handled and disseminated in a manner that supports and advances the values and ideals underpinning WP activities and avoids reinforcing existing stereotypes and barriers to social progress. For example, while research/evaluation should, of course, present an accurate picture of differential attainment, it is at the same time necessary to ensure that that picture represents an argument for positive change (see Section M for further consideration of dissemination).

### 4. SAFEGUARDING

Any research/evaluation study involving the participation of young people, children or vulnerable adults brings with it issues of safeguarding. In addition to ensuring that, where appropriate, participants have given informed consent, safeguarding responsibilities include the need to:

1. Ensure that all researchers/evaluators involved have undertaken safeguarding training. This may be a relatively short online course to familiarise themselves with the key principles and practices of safeguarding.
2. Ensure that all researchers/evaluators are appropriate persons to be working with children, young people or vulnerable adults. This may include an enhanced Disclosure and Barring Service (DBS) check, and appropriate training to work with the participant group.
3. Ensure that the location of any face to face data gathering is appropriate for the participant group and does not increase the potential harm they might experience.
4. Ensure that the participant is aware that there are limits on the confidentiality that can be guaranteed, should they disclose something that indicates past abuse or likely abuse or harm in the future to them or other children, young people or vulnerable adults.
5. Act as a responsible adult in supporting the participant during and immediately after data collection.
6. Redact information that would be harmful to the participant should it be made public (even when pseudonymised).

## J. ANONYMITY AND CONFIDENTIALITY

**This section:**

- **Identifies the need for anonymity and confidentiality in research/evaluation**
- **Identifies some limitations on confidentiality**

### 1. ANONYMITY

By anonymised data, we mean data that cannot identify an individual. You can consider data to be effectively anonymised when it does not relate to an identified or identifiable individual, or it is rendered anonymous in such a way that individuals are not (or are no longer) identifiable.

As noted in Section G, for the ease, safety and security of data storage and distribution, it is important that study teams only collect the data they need (rather than collecting data in the hope that it may prove useful). This is pertinent to Article 5.1(c) of the UK GDPR which states that personal data should be "limited to what is necessary in relation to the purposes for which they are processed" (known as the principle of "Data Minimisation") and data anonymised at the earliest possible opportunity (see ICO guide on Anonymisation and subsequent guide on How to Ensure Anonymisation is Effective).

Many types of large scale studies lose nothing by being completely anonymised at the point of data collection. Researchers/evaluators should consider whether any data that identifies an individual needs to be collected for that particular study or whether this can be designed out in line with UK GDPR Article 25

on data protection by design and default, considering the principle of Data Minimisation. For example, in single-data collection studies, such as a questionnaire to gather pupils' views on careers in STEM subjects, researchers/evaluators should start from a presumption that data that identifies an individual is not needed. Where non-anonymised data needs to be stored, then study teams need to seek advice from a Data Protection Officer or qualified data protection professional and follow data protection legislation (UK legislation).

Additionally, researchers/evaluators should be alert to potential breakdowns of anonymisation such as the possibility of 'singling out' an individual. 'Singling out' means that one individual can be distinguished from others in a dataset. For example, a primary school child may be the only child in their school year who is both of a particular ethnic origin and a particular religious affiliation. An 'anonymised' dataset collected from the relevant school year that includes data on ethnicity and religious affiliation may effectively enable that individual to be isolated or singled out and, therefore, identified.

It is worth noting that, in such a case, it may not be easy to predict in advance how and why anonymisation could break down, since any actual case may throw up entirely unanticipated combinations of factors. The ICO refers to this as the 'spectrum of identifiability' where, although data is anonymised, the ability to identify individuals in practice can be highly context-specific. The ICO states that "if there are means 'reasonably likely' to be used to identify someone, then you must view the information as personal data."

Researchers/evaluators who promise anonymity or confidentiality to their participants should be diligent in ensuring such promises are upheld (see HESA guidance on rounding and suppression of data) in alignment with the Data Privacy Notice(s) they have displayed to individuals. It is considered breaking the law to say one thing to an individual about the processing of their data and then do another without being transparent and informing them.

## 2. CONFIDENTIALITY

To protect and preserve the confidentiality of information means to ensure that information is not made available or disclosed to unauthorised individuals, entities or processes. There are several ways of preserving confidentiality, one of which is anonymisation at the point of collection of data, although this may limit your ability to match datasets.

Some types of study may require personal data to be collected in such a way that it could be used to identify individuals. For example, where you want to employ a pre-intervention and post-intervention design and need to identify the same individuals in two data collection instruments, or when the personal and identifying data of participants is important for the study. The confidentiality of identifiable data can be preserved through the use of pseudonymisation, where the identifiable data is attributed a code or number upon collection and very few individuals conduct the pseudonymisation and/or have access to the re-identification key.

### Example

If the study requires two data collection instruments to be linked, each participant could be given a number which identifies their data. The researcher/evaluator holds a key which links the number with the participant's details. This key is held securely and separately from the dataset itself. The dataset would then appear to be anonymous but, when needed, the data from the two instruments could be combined.

This pseudonymising of the data, if conducted securely, means that only a limited number of people will know the identity of participants. These people need to be aware of their responsibility to maintain the confidentiality of such information.

### 3. LIMITED CONFIDENTIALITY

As well as anonymity, it is normal to offer limited confidentiality to participants. Broadly, this is an undertaking that nothing said to the researchers/evaluators will go any further and the researcher/evaluator will not act in a way that makes known what was said by the participant.

In many circumstances, this is limited. In a case where the participant says something that indicates that they may be at significant harm, or that they know about a future illegal activity or of significant harm to other people, the researcher/evaluator is freed from maintaining confidentiality. Where confidentiality is limited, participants must be told this in the information sheet and prior to any interview or focus group.

## K. USING STUDENTS/PUPILS AS CO-RESEARCHERS

**This section:**

- **Explores the implications of recruiting and utilising peer researchers**

It is common to employ students or pupils as peer co-researchers in a study in either paid or voluntary capacities (see the Involve guide). There are obvious advantages in designing data collection, analysis and dissemination in such a way that peers talk to each other, to gain the cultural insights that peer researchers provide (see ICS). If peer co-researchers are to be paid, then study teams should familiarise themselves with the legal issues of employment, especially where peer co-researchers are under 18 years old (see UK government). Additionally, the employment of peer co-researchers should not oblige them to be involved as participants within the study.

### 1. TRAINING AND SUPERVISION

Peer co-researchers should receive appropriate training, support and supervision for their role. They must be able not only to conduct elements of the study, such as running a focus group, but to do so ethically. Training and support may therefore need to include the possible harms involved in the study and how the researchers are expected to respond. For example, if a participant in a focus group makes a comment they find racist or misogynistic, should they challenge that statement or let the focus group continue without interruption? Should they note the incident and challenge it later, or report it explicitly to their supervisor? These are the types of questions that would need to be considered during training, before involving peer co-researchers in a study.

### 2. ANONYMITY AND CONFIDENTIALITY

The value of peer co-researchers is their closeness to the participant population (and often their membership of it). This closeness, however, increases the risk of confidential information gathered during the study becoming publicly known. This is not only a risk for peer co-researchers; for example, interviewing higher education colleagues gives researchers/evaluators information that they must pretend not to know in other aspects of their work. However, the risk for peer co-researchers working on studies located within their communities or networks is heightened for two reasons.

Firstly, peer co-researchers should be trained in the need for confidentiality in relation to what is said during the study – both in their dealings with participants and within the research/evaluation team. Training will give them strategies to cope with situations where confidentiality may be difficult to maintain, and to identify those situations where breaking confidentiality is legitimate (e.g. in relation to future illegal acts, or possible harm to the participant). The strategies needed will depend on the relationship between the peer co-researchers and the participant population. For example, if the peer co-researchers are students at the same HEP as the participants, this will give rise to different issues than if they are students at another HEP some distance away.

Secondly, peer researchers need to be supported in discussing anything heard as part of the study that concerns them, their friends or those on their course of study. If they hear something of significance, social rules may allow this to be used to their or their friends' advantage, potentially breaching confidentiality. This raises ethical issues for the peer co-researcher beyond the limits of the study.

### 3. COERCION

One of the advantages of employing peer co-researchers is that participants often feel freer to talk to a peer than to an older adult. Ethically, this could be seen as blurring the lines with the coercion of participants against their best judgement. For example, a study team recruits popular students at school as peer co-researchers. They then leverage this popularity to recruit other students at the school into their study. As with the broader discussion on incentives (see Section G.1), there is a judgement to be made. As a study team, you will often want your research/evaluation to be a pleasant experience, but it should not be so attractive that potential participants act against their best interests.

## L. COLLECTING DATA IN PUBLIC SPACES (ONLINE AND IN PERSON)

**This section:**

- **Affirms the accepted principle that public behaviour can be observed and reported without the need for consent**
- **Considers the ethical issues and limitations embedded in this principle**

It is an established principle in social research/evaluation that individual consent is not necessary in cases where the researcher/evaluator is observing public behaviour. In many cases, the categorisation of behaviour as 'public' or 'private' will be straightforward. However, the researcher/evaluator needs to be sensitive to two issues: what constitutes public space in this principle and the recognition that not all behaviours in public space are public.

It is worth noting that when conducting "systematic monitoring of a publicly accessible area on a large scale", the researcher/evaluator is legally required to conduct a Data Protection Impact Assessment (DPIA). The UK GDPR does not define "large scale" although the ICO provides considerations and examples on their website.

Researchers/evaluators must take into account, when designing data collection activities, how they will distribute and display a Data Protection Notice/Data Privacy Notice to individuals, whether or not they are collecting data directly from the individuals.

### 1. PUBLIC/PRIVATE SPACES

Some spaces are generally seen as public; in these, most people would expect to be observed by others whom they do not know and feel able to act relatively freely, for example when walking along the street or drinking coffee in a café. Other spaces are generally agreed to be private, for example inside one's own home. I might invite visitors into this space and still be observed. Such an invitation to researchers/evaluators would be an *act of consent* as long as the participant had been informed of the purpose of the researcher's/evaluator's visit.

There are, however, various intermediate cases where the boundary between public and private is less well defined. An invitation-only social event may or may not be a private event; a hospital or a public toilet may be a public building but most of us would expect our 'privacy' to be respected. School classrooms and HEP campus buildings are often dual spaces – both private and, in limited ways, public. For example, students attending a lecture are not free to choose – they need to be there. As such, a lecture room does not seem to be obviously 'public' in terms of research/evaluation.

Such complications also affect online environments. Online platforms and chatrooms may or may not be restricted in terms of who can contribute and who can access chats but not contribute to them. 'Publishing' our holiday snaps on social media may or may not be regarded as 'publishing' in the conventional sense, depending on the precise platforms and protocols involved (see Social Media Research: A Guide to Ethics). In such cases, *contextual integrity* (Section H) may be helpful.

## 2. PUBLIC/PRIVATE ACTS

An additional way to think about this is in terms of the nature of the act. For example, an individual may expect privacy in a public toilet, but perhaps not if the toilet block is being used as part of a pop-up theatre. A community park may be a public space, but there are occasions when individuals and groups seek to hide from the public gaze to engage in private activities (e.g. when receiving emergency medical help or emotional support). Thus, as well as the nature of the space, there is a need to be aware of the nature of the activity taking place.

A key point is that while genuinely public behaviour is often easily accessible to observers, the converse does not hold: while what is public may always be accessible, it does not follow that what is accessible is always public.

### Example

A study may seek to collect data on discussions about career and higher education aspirations between pupils during lunchtime. To this end, observers sit in the playground at the school. Is this a private or a public space? If the study moves to the local fast-food restaurant frequented by pupils after school, does this make the study more ethical, as the space would normally be seen as more public? What about observations in a public park?

Would the situation change if, instead of education matters, the observers were in the park studying pupils' sexual behaviours (perhaps testing a hypothesis of the negative relationship between higher education aspirations and early engagement in sexual activities)?

In schools and HEPs, therefore, observing in 'public' spaces is problematic. Many of the formal spaces used by pupils and students – such as classrooms, lecture rooms or laboratories – are unlikely to be public in the sense intended by the principal. Other spaces, for example, onsite cafes or the library, are potentially 'public' and individuals may well expect that their behaviour and talk will be observed. When justifying a study using this principle, a study team would be expected to outline the types of behaviour they will be collecting as data, the types of behaviour they will ignore, and how they will remain compliant with the principle of transparency in data protection terms through the requirement to keep individuals informed about their use of data.

# M. THE ETHICS OF RESEARCH/EVALUATION DISSEMINATION

**This section:**

- **Identifies some of the key ethical issues in disseminating research/evaluation**

Having completed the research/evaluation study, there remain a number of ethical obligations to participants regarding how the findings are disseminated. These include:

- Fulfilling the commitments that you gave to participants in the information you provided
- Ensuring the truthfulness and completeness of the claims that you make
- Ensuring that social groups, especially vulnerable groups, are not misrepresented in the findings
- Ensuring that the impact of the research/evaluation is both justified and maximised

## 1. FULFILLING THE COMMITMENTS TO PARTICIPANTS

If the study team has provided information to participants – on a fully informed basis, partially informed with debrief, or an offer to opt out or assent – then it will have made some commitments to the participants about how their data will be used and destroyed. It may also have made some broader commitments about the value or use of the findings, for example, that the data will be deleted after five years or that the findings will be used to inform university policy. Commitments may also have been made about the anonymisation of the data and any sharing of the data set after the study.

The study team should have processes in place to ensure they are following through on any commitments. For example, they should maintain a data destruction log (see the University of Dundee's example) to track how the data gathered will be destroyed. It should also be clear who is responsible for this process.

Even where no explicit commitments have been made to the data subjects, there may be some implicit commitments. If *contextual integrity* (see Section H) has been employed as a justification for gathering data, then there may be implications for how the data should be used in disseminating the research/evaluation. For example, if Twitter data was used, then it would be reasonable that any dissemination should maintain the same structure of an asynchronous discussion with other contributors to a thread rather than as a single comment to the original post.

## 2. ENSURING THE TRUTHFULNESS AND COMPLETENESS OF THE CLAIMS

Part of the social contract of involvement in research/evaluation is that the researchers/evaluators are competent to use the data gathered appropriately and skilfully. Study teams should demonstrate academic integrity in presenting the data they have collected, drawing conclusions from it, and exploring the implications for practice. In part, this is a matter of ensuring adequate skills and training amongst the study team for the kind of study conducted, and a collective commitment to developing a strong evidence base for practice.

Alongside the ethical obligation for truthfulness is an obligation for completeness. While remaining truthful, the evidence constructed in a study may be only partially disseminated, giving a distorted picture of what was found, and potentially supporting practices that the evidence does not. A common form of incompleteness is where the evidence from a study shows that a new intervention has a negative impact on a subgroup of the population studied, but the negative data is not reported (e.g. in early studies of facial recognition software).

## 3. ENSURING THAT SOCIAL GROUPS ARE NOT MISREPRESENTED IN THE FINDINGS

In some studies, it is possible to build ever more detailed pictures of communities and social groups, leading to a serious risk that the data will be read as if it were a portrayal of a natural formation rather than a socially constructed one, for example, the implication that Black males are less interested in academic work and success. This is a particular risk for social research/evaluation of the type undertaken in WP, which is distinctly political and sensitive to the political or ideological commitments of commissioners, researchers/evaluators and readers.

Despite the best intentions of researchers/evaluators, the results of their work may lead to the establishment of a stereotyped representation of a community or other social grouping. While stereotypes are not true portrayals of the relevant social groups, there is no reason why a stereotyped conception of a social group should not predominantly consist of true beliefs.

For example, according to a stereotype, a given social group may be held overall to be notably under-educated. Detailed research/evaluation may reveal that the stereotype is essentially correct: overall, the group is relatively under-educated. For example, some social groups do not have a high level of formal qualifications. The point of researching/evaluating such a state of affairs may be to help bring about the required social change to ensure that, in the future, no group should be in such a position. However, data that 'confirms' an existing stereotype is double-edged: to those committed to change it will be a call to action, but to those tempted to naturalise prevailing stereotypes it may appear to confirm their prejudices.

The danger is that increasingly detailed data concerning the differential educational attainment of various social groups may seem to constitute an argument for concentrating resources and opportunities where they will not be 'wasted'. As always, the data is not self-interpreting, and researchers/evaluators committed to WP goals and values should be mindful of the potentially negative consequences of releasing data that can be subject to interpretations that are notably at odds with the values and commitments of WP practice (see Section B above)

## 4. ENSURING THAT THE PRACTICAL IMPACT OF THE RESEARCH/EVALUATION IS JUSTIFIED AND MAXIMISED

Participants have committed time, energy and resources to the study, usually because they believe that the study is important and will inform future WP practice. Study teams ought to ensure that they have thought about how they will bring their findings to the attention of those responsible for effecting change.

Such *pathways to impact planning* are often part of research studies (see Cambridge University's 'Pathways to Impact').

# N. THE ETHICS OF EXPERIMENTAL DESIGNS

**This section:**

- **Identifies the specific considerations emerging from experimental research designs**
- **Develops earlier discussions on informed consent and data security**

Experimental Research designs include randomised controlled trials (RCTs) and Quasi-experimental research designs (QEDs).

Different experimental designs carry different risks, as do the different institutional contexts within which the study is conducted. For example, RCTs comparing two or more interventions (i.e. without a control group) do not have to address the ethics of running control groups. A HEP running several large experimental studies to aggregate the data must address the risk that combining the different data sets may cause additional challenges with anonymity and confidentiality.

## 1. WHAT ETHICAL CHALLENGES DO THEY RAISE?

Experimental designs are classified as 'research' rather than 'audit' as they seek to test a hypothesis. They share all the ethical issues of other research methodologies, exacerbate the potential risks of some issues and generate new ethical issues due to their design. Experimental designs do not need to be complex nor more ethically problematic. In fact, their focus on research design allows for good ethical practices to be designed into the study. However, the more complex the design, in general, the more detailed the ethical reflection will need to be.

### What might make this study ethically more problematic?

- Everyone who applied could have been accepted and some pupils were excluded just so that the study could be conducted.
- Previously, acceptance on the summer schools followed targeted criteria (for example, lowest IMD scores prioritised) because these groups were known to gain more from attendance at a summer school. Some pupils who would have been accepted under this approach are now not accepted because of the study.
- The questionnaires were simply embedded in the summer schools and pupils were not made aware of their right not to complete them.
- The pupils were not thought competent to give their own consent (e.g. because they were too young or especially vulnerable).

In randomised designs, the act of randomisation is usually ethically neutral; however, the implications of that randomisation are sometimes problematic.

### Extended Example

A study is proposed to consider the effect of summer schools on WP pupils' trajectories into higher education. The design is an RCT with a control group. Pupils signing up to a summer school are randomly allocated either to 'be accepted' or 'not to be accepted' for a summer school. At this point, two ethical issues presented themselves: are 'not accepted pupils' necessarily harmed by the randomisation and is the randomisation process unfair? Clearly the two groups of pupils will have unequal treatment, but this is not necessarily unfair.

Given that the study is intended to establish whether summer schools have a positive effect, there is no obvious harm caused to those who are not accepted into the summer school. In this case, there are always more applications to the summer schools than can be accommodated. Previously, the organisers used a 'first come' basis, although they recognised that this advantaged pupils who had strong school or parental support to apply early. The alternative approach, randomising all applicants, was thought to be ethically at least as acceptable (and possibly more so). Overall, the same number of pupils would attend the summer schools as would have done without the study. Further harms might occur due to those who are not accepted believing that they had 'failed' in some way in their application, or a harm due to frustration at having their autonomous choice denied. The study team ensured that all applicants knew that their acceptance, or not, was not something the pupils could do anything about – it was a lottery due to limited spaces. Technical checks were conducted to ensure that the randomising process was not more likely to allocate certain social or school groups into the control group.

Once on the programme, those accepted were asked to complete two questionnaires. Full information was given to the pupils, and their consent was recorded by their submission of the questionnaires. Pupils were also informed that by submitting the questionnaires they were consenting to the study team looking at which HEP they attend (if any) in the future.

Those pupils who were under 16 years of age could apply and attend the summer schools without parental consent being obtained. The study team argued that the Gillick principle should apply to consent for the study – that the pupils were competent to give their own consent. Prior to completing the questionnaires, pupils were given an information sheet for their parents in which parents were informed that they could *opt their child out of the study* by contacting the study team.

## 2. NEW ETHICAL ISSUES – CONTROL GROUPS

### A. Equipoise

A key ethical concern is where a control group design is used and the control group receives the standard or 'business as usual' treatment, meaning that they do not have access to the experience being trialled (e.g. a new educational intervention). *If* there is evidence that this experience is valuable, *then* the study intentionally deprives control group participants. This is an ethical harm that needs to be addressed. 'Equipoise' describes a study in which there is no clear evidence in favour of any arm of the study. No group of participants is intentionally deprived of something of value because it is not known which is the most valuable of the experiences deployed in the study. This principle of 'equipoise' makes the ethical implications *easier to navigate*. Given that we do not know which group (if either) is advantaged, there is no deliberate unfairness in the research/evaluation design.

Most studies are conducted because there is a *belief* that a new educational intervention will be an improvement, or because there are questions over the assumptions built into the usual intervention. In some studies, there is a lack of evidence to justify the belief, hence the need to evaluate/research. In others, it is clear that prior evidence exists for the value of the intervention, and the control group would be unfairly disadvantaged if they were simply not to receive this valuable intervention (see later for ways to resolve this). There is an evidential continuum between *believing* and *knowing*, and a judgement needs to be made by the study team. Believing that an intervention or explanation may be valuable is a good reason for research/evaluation and does not undermine equipoise. Knowing, due to existing rigorous causal evidence, that it is valuable does undermine equipoise.

### Example

A number of years ago some HEPs invited Key Stage 2 pupils to attend 'university experience days'. Given the extended period until these pupils made choices about which school subjects to study and applied to higher education, it was unclear whether these days had any impact on pupils' educational trajectories. Despite anecdotal evidence that teachers thought the days useful, and pupil feedback was positive, nevertheless, there was a lack of evidence of value and a large RCT designed study would have been ethically justifiable.

Given the shift in the evidence base for such interventions, it is unlikely that such a study design would be ethically acceptable today

#### B. Delayed/waitlist intervention designs

Sometimes, however, we conduct research/evaluation because we have strong evidence that **the experimental group will receive some advantage over the control group**, and the study is intended to estimate how large that advantage is. Such studies have clear ethical issues, because one group of participants is, due to randomisation, excluded from receiving the full benefits. This is usually seen as unethical, and a common response is to ensure that the control group has an opportunity to receive the same experience later (often called a delayed or waitlist intervention). Delayed intervention often provides an ethically acceptable way to minimise the unfairness because we are not withholding something that will be needed. The timing of the delayed intervention is important. The delay in receiving the valuable intervention must not be significant; the unfairness must only be temporary.

### Example

There is evidence that mentoring WP students when they arrive at their HEP has positive effects on their achievement. However, there is also strong evidence that this is merely the result of self-selection – students who attend mentoring sessions are, by their disposition, more likely to attend lectures and seminars, and complete set tasks. It is their engagement with their studies that causally affects their achievement, not the mentoring. This latter evidence leads us to judge that we no longer know that mentoring supports such students.

Under these circumstances it would be ethically justifiable to conduct an RCT to establish which body of evidence is most likely to be correct. In this case, care must be taken to ensure that the control group retains access to what we still know to be valuable, e.g. if the mentoring scheme includes study support, then the control group would need to receive the study support, but outside a mentoring relationship

### Example

A study is proposed to investigate support interventions for pupils to make applications to Russell Group Universities. These interventions are known to be effective, but it is unclear how effective and why. The study team proposes a delayed intervention design, with the experimental group receiving the intervention in the first year of their level 3 course and the control group receiving the intervention in the second year.

Ethical scrutiny saw the delayed intervention as too late for the control group students, who would most likely make their UCAS applications in the first few weeks of receiving the intervention. An alternative without control groups was found to be acceptable.

In some forms of RCT, for example, clustered RCTs, groups – rather than individuals – are randomised to receive the intervention (e.g. schools are the units of randomisation but pupils the units of intervention). This is not unique in research/evaluation but *occasionally RCT designs necessitate the inclusion of all members of a group*. In such cases, researchers/evaluators have argued that an individual can give consent for the whole group. The use of such guardian-gatekeepers remains controversial as it conflicts with the principle of respecting individual autonomy. Ethically, the situation has close similarities with covert research/evaluation (see Section E) where the study is allowable because the methodology

requires it, because the study promises very significant benefits and there is little or no risk to the participants at any stage.

Guardian-gatekeepers need to be individuals with some responsibility for the wellbeing of the participants, such as the headteacher in a school and should be able to give the research/evaluation team access to the necessary data.

## 3. SHARED ETHICAL ISSUES

As with other studies, there is a need to consider *consent* (See Section C and D). Some studies do not require specific consent.

### Example

An HEP runs a trial to assess the response rate to an email correspondence to potential students aimed to support their conversion from applicant to holder of a firmly accepted offer. The HEP randomises applicants into three groups to receive different forms of the same email. The HEP will then look at the conversion rates for each arm of the study.

In this case, there does not seem to be any reason to ask for consent from the applicants for this study. The format of the email is a matter for the HEP and the conversion rate data is collected as part of their usual activity. Therefore, although a trial is being conducted, there is no need for consent.

The act of randomising people into different arms of a study does not itself require consent, neither does the aspiration to make the findings of the study public.

Where consent is required, study teams need to apply the processes discussed in Sections C and E. For many experimental designs, the number of participants makes the management of consent more complex. Consent can, however, be recorded in a light touch way; for example, where the research instrument is a questionnaire, then its submission is often sufficient to record consent.

### Example

A quasi-experimental design is used to assess the value of a student support scheme for WP students in their first term in higher education. The support scheme only operates in one-third of the courses on offer. The researchers match the WP students on those courses with a 'control' group on other courses who are WP students and reflect the same demographics. The researchers invite the WP students on the courses with the support scheme and the matched 'control' group to complete an online questionnaire about their experiences in the first term, including their end-of-term assessment grades.

The questionnaire includes a statement about how the researchers will use the data, that participants cannot withdraw after submitting the questionnaire and that submitting the questionnaire will be seen as consenting. Thus, the study used fully informed consent.

## 4. ETHICAL ISSUES THAT ARE EXACERBATED

### A. Data confidentiality

Under UK legislation, anonymised data does not fall under the GDPR (see ICO guide on Anonymisation and subsequent guide on How to Ensure Anonymisation is Effective). Many ethical responsibilities to participants can be resolved by early and rigorous anonymisation of data (not least because it lowers the risk of identifiable data becoming public). However, modern techniques of data handling and processing enable the use of larger data sets in social research/evaluation, which provides new opportunities to develop highly detailed pictures of social groups and educational interventions. Such pictures can inform, and have become influential for, both policymakers and practitioners. However, from an ethical standpoint, such detailed pictures present two significant challenges which are of a more general nature than other ethical challenges in this guidance: maintaining anonymity and ensuring data security.

### B. Anonymisation in large group studies

There is a risk that anonymisation and/or confidentiality may break down when working with large datasets. Intuitively, it may seem that the larger the dataset the more an individual's data will be 'lost' or submerged in the bigger picture. This would support rather than undermine anonymisation. However, if the level of detail in the data increases in line with, or more rapidly than, the number of participants, a large and searchable dataset may, in fact, leave individuals more exposed to effective re-identification than would have been the case with a smaller cohort and a more coarsely-grained analysis.

Research ethics set a high expectation of anonymisation. Any anonymisation must be secure against someone wanting to use the data for unethical or illegal purposes, and not just an average member of the public but someone with a high level of data expertise. (The ICO guide sets out a series of tests to ensure data is maximally anonymised.) Researchers/evaluators need to ensure as far as possible that a motivated intruder cannot use the dataset to re-identify any data subjects from the data or through the use of data from a combination of publicly available sources.

As a simple example, we often ask for the postcode of a young person to check the status of their home address on the Index of Multiple Deprivation (IMD). If we also know that the person is 17 and has two siblings, for example, it becomes easier to identify that specific person. Or, if we have a dataset of students at a university, we can with a relatively small number of separate data items re-identify them. For a more extensive discussion of anonymity, see Section J.

This problem is intensified when datasets from different sources are combined, leading to the potential triangulation of individual profiles from a few important items of data. Thus, when collecting data from large cohorts, careful attention should be paid to the level of detail at which the data is acquired and which may become publicly available, to ensure that any reassurances given to participants concerning anonymisation/ confidentiality can be fulfilled.

### C. Potential data breaches

Large datasets create increased risks around potential data breaches when the data collected can potentially be linked to individuals, either independently or in combination with other available data sets. It is an established rule of thumb for researchers/evaluators – and an integral element of UK GDPR legislation – that data should not be gathered unnecessarily. Studies should be designed to ensure that only data directly relevant to the study is gathered, reducing data storage and security concerns to the minimum practicable level. This principle was relatively straightforward to apply when it was difficult and expensive to gather, store and analyse a large quantity of data. However, this has changed in recent years, as data storage and manipulation have become much easier and cheaper. It may be tempting to gather unnecessary data in the hope that it may be useful.

In addition to this increased risk, data storage and security may be opaque when using cloud-based services, because the study team is dependent on a range of security measures which they do not know. These combined factors underline how important it is that researchers/evaluators adhere to the principle of gathering only essential data, anonymising it at the earliest opportunity and storing it securely. Ideally, anonymisation should be at the point of collection; where this is not possible, study teams should record why this is not the case.

Where a cloud service provider is processing personal data that could be considered a high risk to the data subject – or where there could be material or non-material damage or distress to the data subject – were the data to be exposed. The UK GDPR requires a DPIA to be conducted, to ensure the security of the processing of the data. Should there be a breach of the personal data causing risk to a data subject, the UK Information Commissioner's Office must be informed of the breach within 72 hours of it becoming known. Where there is a high risk to data subjects because of a breach, the data subjects must be notified within 1 month of the breach becoming known.

Where a breach can be mitigated so that it no longer poses a risk to the data subjects, and this can be proved, there is no requirement to inform the ICO. This is a matter for a Data Protection Officer, data protection professional or legal counsel to review before the researcher/evaluator makes a decision, as every data breach – no matter how small – must be logged and a Breach Report written.

# O. USING PRE-EXISTING DATASETS

It is increasingly seen as important, and is a requirement of some funded research/evaluation, to make any dataset produced available to other researchers/evaluators to use in their studies. Such secondary uses of data produce two ethical challenges.

## 1. INFORMED CONSENT

Generally, datasets ought to be shared in an anonymised form, although sometimes it is necessary for them to be in a pseudonymised form, for example, where student identification numbers are required to link data in different datasets. This raises the issue of whether the participant would consent to their data being used in this way. Since it is impossible to go back to the individual participants and ask them, a judgement must be made about their likely agreement. Researchers/evaluators should ask themselves several questions:

**A. Did the participant give or withhold consent for secondary use of their data?**

It is increasingly the case that researchers/evaluators ask participants for consent for their data to be reused in other studies. If participants gave consent for secondary use without limit, then the study has informed consent. Where they have withheld consent, there are good ethical reasons to exclude their data from any further studies.[6]

**B. Was the participant in a position to give informed consent to the secondary data use?**

Given that the consenting individual did not have information about the present study, then it is reasonable to ask whether they imagined their data being used for this kind of study. If the proposed secondary use is in line with, or at least reasonably close to, the original study, then we may assume that the consent was reasonably informed. Where the proposed study is at odds, for example, in terms of its values and ambitions, further consideration is necessary.

Where the dataset is not anonymised, it may still be difficult to find the participants to ask for their consent. In such cases, the researcher/evaluator may well treat the dataset as anonymised but with the added need to maintain confidentiality in processing the data and to maintain anonymity in its publication.[7] Where it is possible to trace participants, for example, information from a study completed a year previously in a school, it may be reasonable for a researcher/evaluator to return to the school to seek consent from participants for the use of the data in their study.

## 2. THE BREAKDOWN OF ANONYMISATION

When reusing datasets, researchers/evaluators should be mindful of the dangers of combining data sets (see Section N) where anonymisation can break down via the triangulation of just a handful of data points. In such cases, study teams should take this risk seriously and consider the likelihood of the datasets they are using potentially enabling the de-anonymisation of the data.

[6] It is worth noting that it may be legal to use the data – and some study teams may decide to progress on that basis. At the moment, the ethical position is that it would be legal on balance, but inconsistent with the UK Research Integrity Concordat.

[7] While this may be ethically permissible, care must be taken to ensure that it is consistent with data protection laws in place.

# P. MANAGING ETHICAL SCRUTINY

**This section:**

- **Offers guidance on conducting ethical scrutiny within an organisation**
- **Offers guidance on how a formal research ethics committee reviews applications**

Throughout this guidance, we have discussed ethical scrutiny. While all audit, evaluation and research activities require ethical reflection by those conducting them, research and evaluation usually also require some ethical scrutiny – often by those outside the research/evaluation team. In large organisations, for example, universities, this is conducted by RECs. Smaller organisations may have one or more people who have skills and responsibilities in terms of leadership of research/evaluation. In either case, the same kinds of scrutiny should be given to study proposals:

- What is the design of the research/evaluation and is it fit for the planned purpose?
- Does the choice of design limit the ethical issues that the study raises?
- Does it treat participants fairly, and are their rights respected: will they give informed consent and, if not, are the reasons for this clear and compelling?
- Have the risks associated with the study been considered, mitigated if possible, and communicated to participants?
- Have the reasons for collecting personal data been justified and documented?
- Are the arrangements for confidentiality, data security and anonymity in any publication clear and well understood by those undertaking the research/evaluation?

For secondary use of data:

- Is the original consent given by participants sufficient for this present study?

## 1. A NOTE ON RECS

RECs have a range of responsibilities: protecting the rights of participants, ensuring compliance with data protection processes and taking a view on any reputational risk to the organisation. A significant role of ethics committees is to assure themselves that researchers/evaluators are thinking about the ethical issues raised by their study.

Most RECs work through the submission of a standard form which is reviewed by two or three members of the committee. Applications can be rejected for a number of reasons, some general and some specific to the project.

Often, REC approvals are mistaken for data protection approval. Researchers may think that data protection requirements are satisfied by REC approval(s) and, consequently, that they can forgo further data protection consideration by a qualified data protection professional or a Data Protection Officer. This is not correct; data protection expertise should be sought for each project in addition to any REC submission or approval processes.

## 2. GENERAL REASONS FOR REJECTION

1. The form shows no evidence of explicit ethical reflection by the applicant. Although the risks may be low, the reviewers cannot see whether this is the result of the applicants knowing how to reduce the ethical issues, and intentionally doing so, or mere chance. Since ethical conduct in research/evaluation is an ongoing requirement, an application needs to demonstrate that the applicants will act ethically throughout the study.
2. The application is unclear about what is going to happen and the justification of the methods used. Given that reviewers do not know your study, or often the specific area of your work, the application needs to explain it clearly enough for them to understand it and form an opinion on how you intend to conduct it. Many applications are rejected not because of ethical issues but because they are unintelligible to the reviewers, for example, an evaluation design that merely states it is pre-/post-test without giving full details of what it will entail.
3. The application, and especially information sheets and consent forms, are full of spelling and typing errors.
4. It is expected that participants will give fully informed consent to be involved. Where this is not the case, a clear argument is needed as to why this is not possible. Reviewers will think about ways in which they think the study could be done with informed consent, so applications need to provide a strong answer.
5. The information provided to participants needs to give all the information they need (and not too much) in a form they can easily understand. Applications are often rejected because the information is not complete or is presented in too complex a format to be understood. In many cases, an ethics committee will have its own proformas; using these usually eases the process. The same is true of the consent form developed for the study.
6. The application gives various possible actions that may be taken. It is difficult to approve an application where it is not clear which of several routes a researcher/evaluator may take during a study. A REC reviewer needs to know what the study team is proposing to do rather than being presented with a selection of options from which the team will choose after approval has been given.

# APPENDIX 1 – UK RESEARCH INTEGRITY CONCORDAT

Universities UK, along with other UK research organisations, is a signatory to the Research Integrity Concordat. This guidance is written with due regard to the expectations of the concordat.

**In summary, the concordat affirms a 'commit[ment] to:**

1. upholding the highest standards of rigour and integrity in all aspects of research.
2. ensuring that research is conducted according to appropriate ethical, legal and professional frameworks, obligations and standards.
3. supporting a research environment that is underpinned by a culture of integrity and based on good governance, best practice, and support for the development of researchers.
4. using transparent, timely, robust and fair processes to deal with allegations of research misconduct should they arise.
5. working together to strengthen the integrity of research and to review progress regularly and openly'.'

# APPENDIX 2 – A SELECTION OF OPEN ACCESS RESEARCH ETHICS GUIDANCE


Ambrose-Oji, Atkinson & Pollard 2020.
SERG Statement of Research Ethics

Association of Internet Researchers 2019.
Internet Research: Ethical Guidelines 3.0
Association of Internet Researchers

BERA 2019.
BERA Research Ethics Case Studies: 3.
Anticipating the application & unintended consequences of practitioner research

BERA 2019.
Ethical Guidelines for Educational Research, fourth edition

Boaden, Gerrisj, Sinfield & Spence 2009.
Guidance on ethical considerations for CLAHRC implementation activity

British Psychological Society 2017.
Ethics Guidelines for Internet-mediated Research

British Psychological Society 2021.
BPS Code of Human Research Ethics

Committee on Professional Ethics of the American Statistical Association 2018.
Ethical Guidelines for Statistical Practice

Council of Europe 2012.
Guide for Research Ethics Committee Members
Steering Committee on Bioethics

Dench, Iphofen & Huws 2004.
An EU Code of Ethics for Socio-Economic Research

Doody & Noonan 2016.
Nursing research ethics, guidance and application in practice

Economic & Social Research Council n.d.
Research Ethics Framework (REF)

Emerald Publishing n.d.
Conduct research ethically

ESRC 2015.
ESRC Framework for Research Ethics (2015 update)

European Commission 2018.
Ethics_and_Data_Protection

Finacial Conduct Authority 2018.
When and how we use field trials

Government of Canada 2021.
The Interagency Advisory Panel on Research Ethics (PRE)

Government Social Research 2021.
GSR_Ethics_Guidance

Her Majesty's Prison & Probation Service n.d.
Research at Her Majesty's Prison and Probation Service

International Institute for Environment and Development 2014.
Research Ethics
IOD PARC 2019.
DFID ethical guidance for research, evaluation and monitoring activities
Laerd dissertation 2012.
Principles of research ethics
Masterton & Shah 2007.
How to approach a research ethics committee | Advances in Psychiatric Treatment
National Disability Authority 2009.
Ethical Principles
NHS Health Research Authority n.d.
Research Ethics Service and Research Ethics Committees – Health Research Authority
NHS Health Research Authority n.d.
What approvals and decisions do I need? – Health Research Authority
NHS National Patient Safety Agency 2007.
Defining Research
OECD 2016.
Research Ethics and New Forms of Data for Social and Economic Research
Oxfam 2020. Research Ethics:
A practical guide – Oxfam Policy & Practice
Social Care Institute for Excellence 2012.
Research mindedness: Ethics and values in social care research
Social Research Association 2021.
SRA Ethics guidance 2021.
Townsend, L. & Wallace, C. 2021.
Social Media Research: A Guide to Ethics
(ESRC Funded and endorsed).
UK Data Service 2017.
Big data and data sharing: ethical issues
UK Data Service n.d.
UK Data Service: The importance of managing and sharing data
UNICEF 2015.
UNICEF Procedure For Ethical Standards In Research, Evaluation, Data Collection And Analysis
World Health Organisation 2009.
Research Ethics Committees: Basic concepts for capacity-building
World Health Organisation 2020.
Guidance for Research Ethics Committees for rapid review of research during public health emergencies

# APPENDIX 3 – METHODOLOGY NOTE AND SUMMARY OF THE INITIAL LITERATURE

## A. Methodology

The guidance was developed through both a rapid review of the literature, including consideration of the range of pre-existing research ethics guidance and a series of consultations with members of the WP community.

Initial literature searches were conducted on key education and health research databases. A further series of searches were conducted on Google and Google Scholar to ensure that guidance literature was collected. Even with very specific constraints, these searches returned over 3 million articles and websites of potential interest. The development team pragmatically reduced this to a manageable list of 67 research ethics guidance documents directly relevant to educational research, with a bias towards UK literature. They also reviewed 340 paper abstracts with a focus on 'big data' and more complex issues in research ethics, of which 74 papers were considered in more detail. The team also considered 34 textbooks on research practice to review the content on research ethics.

The project team conducted six initial interviews with senior researchers in the field to consider the potential content of any guidance material and to identify the types of ethical issues they faced in their work. The elements of the content were reviewed on five occasions by a Delphi study group of 10, and once by members of the TASO Evaluation Advisory Group. The final draft version of the guidance was sent out for general consultation in November 2021. Feedback from each consultation event was used to develop the final guidance documents.

## B. Brief initial summary of the literature

There is general agreement on the type of principles that underpin research ethics practices, emerging from the Helsinki Declaration and reflected in a range of high level national and non-governmental organisation (NGO) reports, for example, in the United States, the Brownlow Report (1978). However, it remains a matter of some disagreement as to whether these principles remain fit for purpose in social scientific research, primarily in the light of changes in technology.

Although there is general agreement on the basic ethical principles: beneficence, non-maleficence, justice and respect for autonomy,[8] the precise wording concerning specific ethics guidance differs.

Whilst some differences are mere semantics, others reflect political and cultural issues. A critical theme sees mainstream research ethics as too committed to individual rights without sufficient consideration of the social contract and the focus on the common good. This has practical implications in, for example, cluster randomised controlled trials (cluster-RCTs). Culturally, it has been argued that research ethics are too wedded to liberal democratic cultures, for example, by those suggesting an ethic based on ubuntu,[9] or by those who argue that some countries, for example China, have cultures that expect more intrusive surveillance.

Guidance documents develop these basic ethical principles and include principles of the value of the research itself. Research should, in this view, be of significant social value, and processes should be put in place to ensure its dissemination (a specific application of the principle of beneficence to the wider community).

Some research ethics guidance emphasises the importance of integrity in the research process and the need to develop researchers' ethical thinking. These are often related to the possibility of deception and covert research activities, or research at the interface of private and public data (for example in online contexts). In this regard, many guidance documents reflect on the key principles in the light of the perceived risks associated with the research. Risk is seen as influencing decisions about the level of consent and the value of the research itself; both should be proportional to the risk to participants. There is some debate as to whether risk can be adequately quantified in certain experimental situations; often the purpose of the research is to establish the consequences of a particular intervention.

In the light of these discussions, research ethics guidance often identifies the role of the ethics committee as critical – the committee offers external scrutiny and an informed review of the risks, mitigations and protocols that researchers intend to deploy. Thus, RECs are identified as a central element of the research ethics environment.

A core principle in most guidance documents is that of informed consent, which is seen as the expected norm that can only be put aside in a limited number of cases. Such cases lie on a continuum from not giving full disclosure, through active deception to covert research. The more the research moves away from fully informed consent, the more rigorous and significant the justification needs to be. Two critical debates continue in relation to larger sample sizes. The first questions the focus on individual consent and moves towards broader social consent, though the mechanisms for this are unclear. Some researchers, specifically concerning cluster-RCTs, suggest clarity around the role of a guardian-gatekeeper who gives or withholds consent on behalf of the group (e.g. the headteacher of a school). There is, however, no agreement on whether this is sufficient or whether some assent is necessary from individual participants.

[8] **Beneficence –** The principle of doing good where possible. In research contexts, this essentially requires that: (1) the proposal research should do at least some good; (2) if the proposed research also involves unavoidable burdens and harms, it should deliver a significant positive balance of benefits over harms.
**Nonmaleficence –** The principle that the absolute level of burden or harm should not be excessive. The principle of nonmaleficence has to be considered separately from the principle of beneficence because its role is to impose a hard limit on the burdens or harms that can be traded off against promised benefits: even if a proposed project promises to produce significant net benefits, it will not be ethically acceptable if the absolute level of burden/harm involved exceeds reasonable limits.
**Justice** – The principle that the burden/harms and the benefits of research should be equitably distributed among affected populations. In particular, no population should be asked to bear excessive burdens for the sake of benefits to which they will not have proportionate access.
**Respect for autonomy –** The principle that – irrespective of the above considerations concerning benefits, harms and burdens, and their distribution – the capacity of research participants to make their own informed and voluntary decisions to participate in research must be respected as a matter of natural right.

[9] A term, sub-Saharan African in origin, indicating that the individual's humanity is only realised with their social, spiritual/ancestral and cultural bonds with others and that the collective predates the individual.

The second debate concerns expectations of privacy and the ownership of data. In certain forms of research, most notably those that use data provided by participants for other purposes, it is often difficult to establish whether the data is public or private and/or whether the participant would expect it to be opened to uses other than its initial use. Some have suggested that contextual integrity offers a more nuanced approach to these questions. Contextual integrity focuses on the 'flow of information', arguing that a flow is appropriate (or ethical) if it conforms to the norms of that type of information flow and acknowledging that these norms change over time.

This account of privacy differs from more traditional approaches to research ethics that focus on the minimisation of data collection, the anonymisation of data wherever possible, and scrupulous care over the security of the data. However, the formal logic of contextual integrity can lead to this three-fold approach in cases where how the data is collected requires high levels of personal privacy. An example of this is where data is collected specifically for a research project where participants consent based on an agreement of privacy.

This debate tends to support the view expressed in several papers that the basic underpinning principles of research ethics remain suitable, but that their operationalisation needs to be reconfigured in the light of the resources available and changes in how research can be conducted. Primarily, this relates to technology, its broader use in society and hence more easily obtainable datasets, as well as its deployment in the research itself – to 'crunch' those datasets. There is some discussion on whether this language is itself problematic, divorcing the 'data' from the 'person'. However, others see it as a helpful distinction in considering the researcher's ethical responsibilities.

The anonymisation of data is recognised as a particular difficulty – in different ways – for both small and big data research. In smaller qualitative studies, anonymisation risks losing the nuance which is its hallmark and a key indicator of quality. In larger quantitative studies, the issue of 'de-identification' is problematic for a number of reasons, not least that there is no robust unanimous agreement on its definition. It is recognised that de-identification is part of a broader set of tools to ensure the safe use of data and that it needs to be seen as on a continuum rather than a binary feature of data. It is also recognised that disclosure risks increase with dimensionality (i.e. the number of variables), the linkage of multiple data sources and the power of data analytics.

Meanwhile, small qualitative studies can often address the difficulties of anonymisation in the information provided to participants. This is more difficult for larger quantitative (and mixed-methods) studies, especially where the data to be analysed was given for other purposes. Some prototype technical solutions to this issue have been reported, but their effectiveness remains unproven.

As noted earlier, a number of these debates reference issues of potential harm as a result of the re-identification of data (by a malevolent genius). Where the harm is negligible, there may be a reason to worry less about this possibility than in situations where harm is more likely. An example of the former in medical research is the posthumous use of data, or, in social science, perhaps relatively old data which refers to a previous (now closed) period of the participant's life.

In addition to this general guidance on research ethics, a range of literature exists concerned with specific groups requiring particular attention. These include people with disabilities, marginalised groups based on age, background, ethnicity or sexual orientation, and those with minimal digital assets, literacy or skills. It is recognised that the inclusion of such groups in research projects should be recognised as essential. The literature suggests the need for researchers to review protocols to be as inclusive as possible and, where feasible, involve members of such groups in the research design.

The issue of research involving children and young people is a specialist area within research ethics. The literature recognises that researching children and young people requires a more detailed consideration of all the issues raised above to ensure a comprehensive approach and to minimise harm, both now and in the future. While not unique, the ethical decisions in these cases are complex, requiring a judgement to be made between competing principles and values.

A final group to be considered are those in a vulnerable position in relation to the researcher (or the organisation commissioning the research). The literature suggests a range of possible safeguards to ensure that participants are giving free and continued assent to the research: that a named guardian takes on the role of ensuring their wellbeing, and that checks are in place to ensure that there is no perception of

favouritism as a result of participation.

The use of secondary data is an area of specialist work. While the reuse of anonymised large datasets is largely seen as uncontroversial (subject to issues of re-identification), the literature does highlight a number of areas for consideration, most notably that researchers must consider the original purposes for which participants gave consent. It would be reasonable to hold, in some instances, that participants would not have given consent for the new research questions proposed.

In summary, despite a considerable overlap in the direction of the guidance and academic papers, there are clear differences resulting from disciplinary/subject specificity (for example, between psychology, sociology, education and computer-human interaction) and differing political accounts of the role and rights of the individual as against those of the community. There is also a difference between guidance – which seeks some agreed harmony – and academic papers, which tend to pursue complex yet relatively rare dilemmas in research ethics. This latter group especially also pursues very specific ethical issues, although this is also true of more specialised research ethics guidance. As a result, rarely is research ethics guidance comprehensive in its coverage of all possible research practices.

# APPENDIX 4 – PIS

## PARTICIPANT INFORMATION SHEET GUIDELINES 1

(This accompanies the Core Document, Sections C, E, and F)

The informed consent process requires that prospective participants, and/or their legal guardians/ advocates, are provided with sufficient information about a research project to make a knowledgeable decision about whether or not they want to take part.

Participant Information sheets (PIS) are an important part of the informed consent process. This document provides a basic template for researchers when designing information sheets for their research/evaluation projects. The following is a suggested template for participant information sheets. You should adjust and populate the template to suit your project and intended audience. Use clear, simple English at all times and avoid abbreviations and acronyms.

While the PIS does not need to be in written form, and alternatives – such as video – may be appropriate, it does need to be clear to potential participants. If you are planning to use a video format, it ought to follow the same structure as a written PIS.

This template is designed primarily for those conducting qualitative interviews with adults or children (where parental consent is also required) from non-vulnerable populations and dealing with non-sensitive topics. You will need to adapt the different sections and information if conducting focus groups or structured interviews. If conducting research with vulnerable populations and/or involving sensitive topics, please see participant information sheet guidelines and template 2 for further details.

### Template 1

1. **Title of Study**
   *The title should be clear, self-explanatory and consistent across all documents referring to the study.*

2. **Invitation Paragraph**
   *Invite the participant to take part in the study and take care to ensure the reader would not feel they are being pressured or coerced. For example:*
   I would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Ask questions if anything you read is not clear or if you would like more information. Take time to decide whether or not to take part.

3. **Who I am and what this study is about**
   *Explain who you are and why you are doing this study. Explain the overall aim of the study. When*

*describing the study take care to be as neutral as possible and avoid suggesting any bias about what you expect the outcomes from the research to be.*

4. **What will taking part involve?**
   *Explain what taking part in the research will involve, including a list of topics that you will discuss and the expected location and duration of participation. If you plan to use audio recording discuss that also.*

5. **Why have I been invited to take part?**
   *Briefly explain the reasons why and how you have chosen to invite participants, and also how many you are seeking to recruit.*

6. **Do I have to take part?**
   *It should be made clear that participation is voluntary and that participants are free to withdraw their participation at any time, without explanation, and without incurring a disadvantage.*

   *For example:*
   *You do not need to take part and there will be no negative consequences if you do not. You are able to withdraw at any time by contacting the study team (contact details below). You can also refuse to answer any question during the interview.*

7. **What will happen if I take part?**
   *In language that can be understood by participants, you should give a frank and realistic assessment of t he possible benefits of the research – do not oversell what the research will achieve. Consider any possible physical or psychological harm that may come to a participant as a result of participating in the research and what you will do should such a situation arise.*

8. **Will my views be kept confidential?**
   *Explain what steps you will take to ensure the confidentiality and anonymity of the participant and any individuals they talk about. Outline the situations in which you may have to break confidentiality: if the researcher has a strong belief that there is a serious risk of harm or danger to either the participant or another individual (e.g. physical, emotional or sexual abuse, child protection concerns, rape, self-harm, suicidal intent or criminal activity) or if a serious crime has been committed. You should also make it clear that non-anonymised data in the form of signed consent forms and audio recordings are collected and retained as part of the research process.*

9. **How will information you provided be recorded, stored and protected?**
   *Explain that the interview will be recorded and outline the arrangements for storing the research data: where it will be stored, security arrangements and who will have access. Also outline the relevant data retention policy. This will vary depending on the nature and needs of your project.*

10. **What will happen to the results of the study?**
    *Detail how the results will be made available to participants, whether the results are to be published and, if so, how and where they will be available. Tell participants that they will not be identifiable from the results unless they have consented to be so.*

11. **Who should you contact for further information?**
    *Include the contact details of the researcher/evaluator, and whom to contact if the participant wants to report concerns – perhaps a research ethics lead in the organisation.*

## PARTICIPANT INFORMATION SHEET GUIDELINES 2

(This accompanies the Core Document, Section E, F, and G)

This document provides guidance and a template for those conducting research with vulnerable populations or involving sensitive topics, and those conducting focus groups or structured interviews. For more information about participant information sheets and basic templates, please consult Simplified Participant Sheet Guidelines and Template 1.

## General information

For most adults, information is normally provided on a sheet that they can take time to read and consider. However, the procedures will sometimes need to be customised, for example when researchers work with children or people who have learning disabilities, cognitive impairments, low levels of literacy or do not speak English fluently. If no special provision is made for these participants, then they are effectively being excluded from the study, and this must be stated in the research proposal and a justification given.

The design of the information sheet must reflect the research study and be accessible to the intended participants. For example, an information sheet for a complex study, or one that carries potential risks (such as discussion of personal information or family background) will need to be relatively detailed, while an information sheet for children may use graphics or photographs rather than just text.

When working with children or vulnerable adults, you may need to produce two versions of the information sheet: one which is accessible to the participants and one intended for the legal guardian (parent, guardian or caregiver). The two versions must be aligned in terms of content and provide sufficient information, in appropriate detail, such that consent is fully informed.

It is important to ensure that participants are able to ask further questions and are provided with details about where they can find further appropriate information on the specific research area. This applies throughout the research process, even after the information sheet has been read and consent has been obtained.

## Working with children

In the UK, people under the age of 18 (16 in Scotland) are classified as children. However, researchers should not assume that all children are vulnerable and incapable of providing consent because of their age. Children under the age of 16 can be capable of making decisions for themselves.

As a consequence of the 1985 Gillick Case, medical practitioners refer to 'Gillick competency' to denote when a child is able to understand the proposed treatment and to make an informed choice in their best interests. While not yet tested in law, researchers have adopted the same approach and will normally seek consent from both parents/guardians and a child who is deemed Gillick competent. There is no set age for Gillick competency; it depends upon the maturity and understanding of the individual.

While consent can be sought from a child who is deemed Gillick competent, it is normally in the best interests of the child not to proceed with participation unless consent has also been given by their legal guardian. However, in some circumstances, the researcher may decide that parents do not need to be informed and/or do not need to consent. Such cases must be justified robustly and are considered by the research ethics committee on a case-by-case basis.

## Accessibility for all

You may need to make provision for participants who are not fluent in the language of the information sheet and consider how to deal with challenges such as low levels of literacy. For example, you may choose to have information sheets translated into other relevant languages and/or use translators when seeking consent. Rather than relying solely on a written format, information may be also delivered verbally, perhaps as a video.

Such provisions need to be factored into the study design and approved by the research ethics committee prior to recruitment. Given the ethical requirement for fairness and justice in recruitment, the decision to make no provision for these participants must be stated in the research proposal and a justification given.

## Template 2

1. **Title of Study**
   *Your study title must be the same on all related documents and should explain the study in simple English. If you have used a short title, make sure that you quote this as well as the full title on your ethics application form.*

2. **Invitation Paragraph**
   Invite the participant to take part in the study and take care to ensure that the reader would not feel they are being pressured or coerced. For example:
   *You are being invited to participate in a research study. Before you decide whether to participate, 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 feel free to ask us if you would like more information or if there is anything that you do not understand. Please also feel free to discuss this with your family or friends if you wish. We would like to stress that you do not have to accept this invitation and should only agree to take part if you want to. Thank you for reading this.*

3. **Who I am?**
   *Explain who you are and why you are doing this study.*

4. **What is the purpose of the study?**
   *In lay terms, with all technical terms and acronyms defined, you should explain why the study is being conducted: the background, aims and objectives.*

   *In exceptional circumstances, researchers may decide not to disclose the purpose of the research at this stage; for example, if disclosure will affect the behaviour of participants in an observational study. Given the impact of non-disclosure on the informed consent process, this should not be undertaken lightly, and the reason for not informing participants of the purpose of the research must be fully explained in the protocol or research proposal that is submitted for further ethical scrutiny. Ethical approval will only be granted in the case of important issues or matters of social significance that cannot be uncovered in any other way. In such cases, participants must be fully debriefed at the end of the research and the debriefing form must be included with your application for research ethics review.*

5. **Why have I been invited to take part?**
   *Briefly explain the reasons why and how you have chosen to invite participants, and also how many you are seeking to recruit.*

6. **Do I have to take part?**
   *It should be made clear that participation is voluntary and that participants are free to withdraw their participation at any time, without explanation, and without incurring a disadvantage.*

7. **What will happen if I take part?**
   In language that can be understood by a lay reader, you should explain exactly what will be asked of the participant and what will happen during the research. For example, you should explain clearly:
   - *what the methods are*
   - *who the researchers are*
   - *who will be carrying out the study*
   - *what the duration/frequency of the study is*
   - *what the participant's responsibilities are.*

   *When writing this section, think about what you would want to know if you were to take part in a research study.*

   *If the research involves any audio/visual recording, this should be made clear on both the information sheet and consent form.*

   *If there is a possibility that the participant's legal guardians (or another professional) may need to be contacted (depending on the type of study), this should also be made clear on the information sheet and consent form.*

## 8. How will my data be used?

*You must inform the participant of the lawful basis for processing their personal data and, if special category data or criminal offence data will be collected, you will need to outline how you will use this data, as well as the lawful basis for such use (please see the GDPR for Researchers Guidance Document and Research Privacy Notice for further guidance on the lawful basis for processing).*

*If you are conducting a focus group then you should add that it will be impossible to guarantee the confidentiality of what is said. You may also add the ground rules, e.g. 'We ask all participants not to repeat what was said by other people after we have finished the focus group'.*

Further information on how your data will be used can be found in the table below.

| | |
|---|---|
| **How will my data be collected?** | *Outline the data collection methods used in the study.* |
| **How will my data be stored?** | *Explain the storage arrangements for the data including whether any data will be stored on external systems and databases.* |
| **How long will my data be stored?** | *Outline the retention period for the type of data collected.* |
| **What measures are in place to protect the security and confidentiality of my data?** | *Outline methods such as encryption and, if necessary, how data will be secured during transfer between field collection/storage/researchers.* |
| **Will my data be anonymised?** | *Explain whether the data will be anonymised and include the details of any anonymisation/pseudonymisation, including when in the research lifecycle this will take place, and (in the case of pseudonymisation) who will have access to the original dataset.* |
| **How will my data be used?** | *Include details on:*<br>*• The types of data collected and what will be done with it*<br>*• Why is the data is used in this way – e.g. why it is necessary for the research outcomes.* |
| **Who will have access to my data?** | *Explain who will have access to the data including the research team. It should also be explained in this section which other organisations you intend to share personal data with (if applicable) – e.g. research partners, 'data processors', any other third-party organisations.*<br>*(A 'data processor' is an organisation or individual who holds or processes data on the research team's behalf.)* |
| **Will my data be archived for use in other research projects in the future?** | *If the data from this project is intended to be open access or stored in your organisation's data bank for future use in accordance with the relevant data management policy, please provide details here.* |
| **How will my data be destroyed?** | *Provide details of when and how the data will be destroyed.* |

### Transferring data outside the EU

If personal data will be transferred outside the European Union, you must explain how this will be conducted, why it is necessary and outline the safeguards in place to protect the data.

## 9. Are there any risks in taking part?

*Explain whether there are any perceived disadvantages or risks involved. Emphasise that, if the participant should experience any discomfort (mental, emotional or physical) or disadvantage as a result of taking part in the research, this should be made known to the researcher(s) immediately.*

*Certain types of research may lead to the identification of serious risks to the participant or others, for example, related to the identification of financial concerns (e.g. severe debt) or legal concerns. If you believe your research could identify such risks, you must have a policy in place for handling the*

*information. Details of the procedure to be followed (for example, will you inform the participant?) must be provided on the information sheet, together with sources of advice and other relevant resources.*

*For example:*

a. *If you are studying consumer behaviour/spending behaviour, you may include a section in the information sheet giving the details of the Citizens Advice Bureau so that participants may contact them for further advice on dealing with debt.*

b. *Consideration should also be given to signposting participants to any local or national support services or helplines that could assist with any other risks to the participant identified during the research.*

10. **Are there any benefits from taking part?**
*It is important to remember that participation in research is typically altruistic; it is on the basis of informed consent (rather than benefit) that we are able to include participants. Of course, we may hope for benefits for participants but, in most cases, we cannot claim that there will be benefits. Unless benefits for participants have been built into the design and can be guaranteed (such as via benefit-sharing agreements), care needs to be taken when describing benefits. Where there is no intended/likely benefit to the participant, this should be made clear.*

11. **Expenses and / or payments**
*Detail any expenses that participants may incur (e.g. travel) and any reimbursement for which they may be eligible. Reimbursement may make participation in your research accessible to more people but should not be so generous as to provide an incentive to take part.*

12. **What will happen to the results of the study?**
*Detail how the results will be made available to the participants. If the results are to be published, state this clearly and describe how and where they will be available. Tell participants that they will not be identifiable from the results unless they have consented to be so.*

13. **What will happen if I want to stop taking part?**
*It is important to remember that informed consent is an ongoing process, not just something that occurs at the start of a study. Consequently, participants must be free to withdraw their participation at any time, and details of how they can do this should be clear on the information sheet. Make it clear that participants do not need to offer any reasons or explanation for why they wish to withdraw from the study.*

*If it is decided that participants will not be given the option to withdraw previously collected data, they should be informed in this section that results or data collected up to the point of withdrawal may be used, but no further data will be collected following the participant's withdrawal.*

*If, after considering the ethical implications of the study, it is decided that participants should be offered the option to withdraw previously collected data, it is still recommended that participants are advised that data collected up to the period of withdrawal may be used if they are happy for this to be done. Otherwise, participants may request that their data be destroyed, and no further use is made of it. If data is anonymised, you should make it clear that it can only be withdrawn before anonymisation; afterwards, it will not be possible to tell which data belongs to which person. Additionally, once data has been collated and/or reported, it may not be possible to isolate and extract. In such circumstances, you should provide a period after which it will not be possible to extract the data.*

*You should provide details of how participants can withdraw their information, explain who should be contacted and highlight any limitations on the withdrawal of information (for example, if the data has been fully anonymised, collated and/or reported).*

14. **What if I am unhappy or if there is a problem?**
*A complaints procedure must be made clear in the PIS. All complaints will normally go through a relevant ethical scrutiny unit in your organisation. You should use something similar to the following wording to explain how complaints will be handled:*

If you are unhappy, or if there is a problem, please feel free to let us know by contacting [main researcher's name and number] and we will try to help. If you remain unhappy or have a complaint which you feel you cannot come to us with, then please contact [...].

*Sometimes it may be necessary to put alternative/additional processes in place for dealing with complaints. For example, when conducting research in another country or with individuals who may struggle to use email, an email contact on the information sheet may not suffice. Complaints processes and procedures must be truly accessible for all, and this may require a tailored approach to individual circumstances. Whatever process is put in place for complaints, it must be clearly specified in the information and approved by the research ethics committee.*

15. **Whom can I contact if I have further questions?**
    You should give the name, address and contact telephone number of the main researcher.

16. **Contact details of investigatory team.**

## Notes: Optional sections (choose as appropriate)

### Disclosure Barring Service check (DBS)

If the research involves vulnerable people (such as children, the elderly or those with learning disabilities), you will usually need to obtain a DBS check. You may therefore want to make a short statement to explain that the researchers involved have obtained a DBS check and that research participants may request evidence of the DBS from the Principal Investigator.

### Discussing sensitive or distressing topics

If the research involves the potential disclosure of personal or sensitive information, you should explain the potential risk of emotional distress and emphasise that participants can abstain from answering any questions they may be uncomfortable with.

You should explain the procedures in place to manage a situation where participant distress occurs (for example, pausing the interview to provide time for participants to consider whether to continue or withdraw from the study). You should also state the sources of support that you can provide/refer participants to (e.g. counselling or local/national support services).

### Disclosure of criminal activity and other confidentiality issues

If you are carrying out research where you may collect information with the potential for disclosure of a criminal activity (e.g. research with young offenders/prisoners), or where there is the potential for other areas of concern to be raised (e.g. concerns about the safety or welfare of the participant or others, for example, in research around domestic abuse) you should inform participants that confidentiality may not always be assured. For research involving young offenders or prisoners, please also ensure that you have discussed with the Prison or Young Offender Institution an appropriate reporting procedure to follow if such information is disclosed.

Template 3

**Example 1 for age group 8–10:**

## 'BREAKFAST, LUNCH AND FEELING FULL'

Hello, my name is [A] and I'm from [your organisation]. I am visiting your school today and I am interested in finding out what kind of breakfast, snack and lunch makes you feel more full. Please have a look at this leaflet which tells you about this study.

## INFORMATION SHEET FOR YOU!

| | |
|---|---|
| **What is the study about?** | **This study is to find out what kind of breakfast, snack and lunch makes you feel more full!** |
| **Why have I been chosen?** | **You are very important – with your help, I can learn more about this!** |
| **What will happen if I take part?** | **1. I will visit you four times at school. Each time I will ask you to eat a different kind of breakfast, snack and lunch and I will ask you how full you feel and if you liked what you ate.**<br>**2. I'll also ask you to fill in a few short questionnaires (I will explain what to do before each one and can help if you get stuck).**<br>**3. The last time I visit I will see how tall you are and what you weigh (no-one else will see this).** |
| **Can I stop if I don't want to do the study anymore?** | **Yes, you can stop at any point if you don't want to take part anymore. You don't have to say why.** |
| **Will the things I write be kept secret?** | **Yes, we will put a number on it but not your name. No-one will know who you are when we write about this study.** |

# APPENDIX 5 – CONSENT

## CONSENT FORM GUIDELINES

(This accompanies Core Document, Sections E, F, and G)

The informed consent process requires that prospective participants, and/or their legal guardians/ advocates, are provided with sufficient information about a research project to make a knowledgeable decision about whether or not they want to take part. Consent forms can be provided together with the information sheet but consent should not be sought until after the participant has read and had time to consider all the information provided.

This template is designed primarily for those conducting qualitative interviews with adults from non-vulnerable populations concerning non-sensitive topics, or children where parental consent is also being sought. The points listed on the template below are for illustration only. You may alter the wording to suit your project as you see fit. For example, the form would be different in the case of focus groups or quantitative research. If conducting research with vulnerable populations and/or sensitive topics, please see Templates 5 and 6 for further details.

A consent form is not simply a means for an individual to give you permission to involve them in research/ evaluation; it is an agreement between the researcher/evaluator and the participant outlining the roles and responsibilities each has towards the other throughout the process. The researcher/evaluator should retain one copy of the consent form signed by both themselves and the participant. The participant should also be given a copy of the consent form as a record of what they have signed up to.

## Template 4

**[Title of project]**

**Consent to take part in research**

Please tick box

- ☐ I..... voluntarily agree to participate in this research study.
- ☐ I understand that even if I agree to participate now, I can withdraw at any time or refuse to answer any question without any consequences of any kind.
- ☐ I understand that I can withdraw permission to use data from my interview within two weeks after the interview, in which case the material will be deleted.
- ☐ I have had the purpose and nature of the study explained to me in writing and I have had the opportunity to ask questions about the study.
- ☐ I understand that participation involves [outline briefly in simple terms what participation in your research will involve].
- ☐ I understand that I will not benefit directly from participating in this research.
- ☐ I agree to my interview being audio-recorded.
- ☐ I understand that all information I provide for this study will be treated confidentially.
- ☐ I understand that in any report on the results of this research my identity will remain anonymous. This will be done by changing my name and disguising any details of my interview which may reveal my identity or the identity of people I speak about.
- ☐ I understand that disguised extracts from my interview may be quoted in [list all areas in which you plan to use the data from the interview, such as a dissertation, conference presentation, published papers].
- ☐ I understand that if I inform the researcher that I or someone else is at risk of harm they may have to report this to the relevant authorities. They will discuss this with me first but may be required to report with or without my permission.
- ☐ I understand that signed consent forms and original audio recordings will be retained in [specify location, security arrangements and who has access to data] until [specify relevant period].
- ☐ I understand that a transcript of my interview in which all identifying information has been removed will be retained for [specify relevant period].
- ☐ I understand that, under freedom of information legalisation, I am entitled to access the information I have provided at any time while it is in storage as specified above.
- ☐ I understand that I am free to contact any of the people involved in the research to seek further clarification and information.

*Signature of participant* .....

*Signature of parent/guardian* .....*Date* .....

*Relationship to participant* .....

I believe the participant and their parent/guardian are giving informed consent to participate in this study

*Signature of researcher* ..... *Date* .....

## Template 5

(Simplified consent form)

**[Title of project]**

**Consent to take part in research**

Please tick box

- ☐ I..... am happy to participate in this research study.
- ☐ I understand that I can withdraw or refuse to answer any questions.
- ☐ The researcher/evaluator has explained the study to me.
- ☐ I agree to being recorded and that only the researchers/evaluators will listen to this recording.
- ☐ I understand that the researchers/evaluators will not tell others what I say.
- ☐ I understand that the researchers/evaluators will write about what I tell them, but no one will know that the information came from me.
- ☐ I understand that if the researcher/evaluator thinks that I or someone else is in danger that they may have to report this. They will discuss this with me first but may be required to report with or without my permission.
- ☐ I understand that signed consent forms and audio recordings will be retained safely until [specify relevant period].

*Signature of participant* .....

*Signature of parent/guardian* .....*Date* .....

*Relationship to participant* .....

I believe the participant and their parent/guardian are giving informed consent to participate in this study

*Signature of researcher* ..... *Date* .....

If you have any questions, please ask me!

Thank you for reading about my study.

TASO

Transforming Access and Student Outcomes in Higher Education

Evidence Quarter
Floor 4, Albany House
94-96 Petty France
London SW1H 9EA

info@taso.org.uk
taso.org.uk

**TASO** is an independent charity that aims to improve lives through evidence-based practice in higher education (HE). We support HE professionals through research, toolkits and evaluation guidance on what works best to eliminate equality gaps. We inform practitioners of the best available evidence and produce new evidence on the most effective approaches. TASO is an affiliate 'What Works' centre and is part of the UK Government's What Works Movement.