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BPS Code of Human Research Ethics

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1. Background

This edition of the British Psychological Society *Code of Human Research Ethics* has been substantially revised and updated from the 2014 edition. Although the changes reflect developments in the field of research ethics, the basic Principles remain unchanged. This new version is intended, as were previous editions, to help psychology researchers to engage actively in identifying, analysing and addressing the range of ethics issues that are pertinent for their particular projects. While many issues are perennial, and this Code seeks

to identify these and provide guidance in how to satisfactorily manage them, new research topics and methods are constantly generating new ethics challenges. So this Code also seeks to engender a mode of thinking that will enable researchers to competently and confidently approach carrying out their investigations in ethically sound ways. In addition, this Code sets out the Society's expectations for how ethics review is best conducted so that participants can be assured that any research they take part in has been properly scrutinised.

1.1 INTRODUCTION

This *Code of Human Research Ethics* is founded on a set of general principles that are applicable to all research contexts and are intended to cover all research with human participants. Principles of conduct for psychologists in professional practice and working with non-human animals are to be found in the Society's *Code of Ethics and Conduct* and other advisory documents prepared by the Society (such as the *Guidelines for Psychologists Working with Animals*).

Ethical researchers prioritise respect for the rights and dignity of participants in their research and also consider legitimate interests of stakeholders such as funders, institutions, sponsors and publics.

There are clear moral and societal imperatives for behaving ethically. Participants in psychological research should have confidence in the investigators; good psychological research is only possible if there is mutual respect and trust between investigators and participants.

Psychological investigators are potentially interested in all aspects of human behaviour and experience. However, for ethics reasons, some areas of human experience and behaviour may be beyond the reach of experiment, observation or other form of

psychological intervention. Ethics guidelines are necessary to clarify the conditions under which psychological research can take place. However, as stated in the *Code of Ethics and Conduct*, '...no Code can replace the need for psychologists to use their professional and ethical judgement' (2018, p.2).

The principles outlined in this *Code of Human Research Ethics* supplement the general ethics principles in the Society's *Code of Ethics and Conduct*. Both sets of principles are tools for making reasoned judgement. Members of the Society are expected to abide by both the *Code of Ethics and Conduct* and also this *Code of Human Research Ethics*. Members should also draw the principles to the attention of research colleagues who are not members of the Society. Members should encourage colleagues, other organisations with whom they work and all researchers whom they supervise (e.g. research assistants and postgraduate, undergraduate, A-level and GCSE students) to consult and if appropriate adopt them.

Additional guidance on specific aspects of psychological research ethics can be found on the Society's website (www.bps.org.uk), including the Society's guidance on ethics in internet-mediated research and in neuroscience. Queries about research ethics that cannot be answered by reference to this *Code of Human Research Ethics* or the

additional guidance on the Society's website, can be addressed to the Society's Research

Ethics Reference Group via research-ethics@bps.org.uk.

1.2 DEFINITIONS OF TERMS

Throughout this *Code of Human Research Ethics*, the following terms are used:

'Research' is defined as any form of disciplined enquiry that aims to contribute to a body of knowledge or theory.

'Research ethics' refers to the moral principles guiding research from its inception through to completion and publication of results.

'Research Ethics Committee (REC)' refers to a multidisciplinary, independent body responsible for reviewing research proposals involving human participants to ensure that their dignity, rights and welfare are protected. The independence and competence of a REC are based upon its membership, its rules regarding conflicts of interest and on regular monitoring of and accountability for its decisions.

'Protocol' refers to a filed document which specifies for a research project the procedures for recruiting participants and gathering and managing data, with which all project staff agree to comply.

'Human participant' is defined as including living human beings, human beings who have recently died (cadavers, human remains and body parts), embryos and foetuses, human tissue and bodily fluids and human data and records (such as but not restricted to medical, genetic, financial, personnel, criminal or administrative records and test results including scholastic achievements). In respect

of data and records, current data protection legislation should be routinely consulted.

'Participant' It is now common practice to refer to a person who provides data for research as a 'participant'. This recognises their active role and replaces the term 'subject' which has been viewed as portraying people as passive rather than active agents. While the extent of active 'participation' in the research over and above providing information will vary greatly from one project to another, the use of the term 'participant' also serves to acknowledge the autonomy and agency of the individual in contributing to the research, and their right to withdraw without penalty. We recognise that the term 'subject' is used in certain contexts, such as describing research designs (e.g. 'within-subjects designs').

In psychological research it is also relevant to acknowledge that a participant's understanding of the experience they have while taking part in the research will often be a valuable additional source of information and may well help to enrich the interpretation of findings.

People other than the individuals who are primary data sources may also need to be included in the consideration of the ethics of research. For example, parents and other relatives, and friends and colleagues, and communities may potentially be affected by research, and the ethical conduct of research will often need to be informed by the interests of other stakeholders as well.

1.3 WHY PRINCIPLES?

Research that involves humans addresses a wide range of topics and utilises many different methodologies. The types and severities of risks associated with human research range widely; from innocuous, de-identified data gathering on non-sensitive topics, to research

carrying multiple high-level risks that demand very detailed ethics protocols and close attention to risk obviation, minimisation and management, along with the necessity for adequate liability cover. Human research also involves a wide variety of populations, some

of which are vulnerable, lack full competence to consent or are otherwise associated with heightened risks. Increasingly, human research crosses institutional, professional and national boundaries, bringing further complication into the application of appropriate ethics protocols and review processes.

For these reasons, the development of detailed and specific regulations on the handling of ethics issues in human research by researchers, with the laudable but implausible aim of covering all eventualities, is seen by many ethicists as an ultimately flawed direction of travel. For example, as soon as one new set of regulations is finalised, a new method or topic of research is likely to emerge that is not covered. The existence of lengthy, detailed and prescriptive professional or institutional regulations raises the risk of researchers following the letter, but not the spirit, of the regulations and may in consequence lead to research being carried out that is ethically unsatisfactory. Overly detailed regulations may also make it more difficult for Research Ethics Committees (RECs) to engage with the nuances of the ethics of individual cases.

A solution to such serious issues is a return to 'first principles'. Ethical research conduct is, in essence, the application of informed

moral reasoning, founded on a set of moral principles. In common with the Society's *Code of Ethics and Conduct*, this *Code of Human Research Ethics* introduces the notion of underlying principles to inform psychological research practice. By openly stating the values that underpin our profession, at this historical point, we make them available for discussion and debate, as well as allowing the possibility of clarification and change.

Moreover, locating the responsibility for developing adequate ethics protocols firmly and squarely with researchers themselves can be achieved by appealing to explicit, core principles at a sufficiently high level of abstraction that the likelihood of individual cases falling outside of them is minimal. It is in this spirit that the following principles have been developed:

Respect for the autonomy, privacy and dignity of individuals, groups and communities.

Scientific integrity.

Social responsibility.

Maximising benefit and minimising harm.

2. The Principles

2.1 RESPECT FOR THE AUTONOMY, PRIVACY AND DIGNITY OF INDIVIDUALS, GROUPS AND COMMUNITIES

Value statement: 'Psychologists value the dignity and worth of all persons, with sensitivity to the dynamics of perceived authority or influence over persons and peoples and with particular regard to people's rights' (*Code of Ethics and Conduct*, 2018, p.5).

Rights to privacy, self-determination, personal liberty and natural justice are of particular importance to psychologists, and they have a responsibility to protect and promote these rights in their research activities. As such, psychologists have a responsibility to develop and follow procedures for valid consent, confidentiality, anonymity, fair treatment and due process that are consistent with those rights.

Ethics standards: Psychologists have and show respect for the autonomy and dignity of persons. In the research context this means that there is a clear duty to participants. For example, psychologists respect the knowledge, insight, experience and expertise of participants and potential participants. They respect individual, cultural and role differences, including those involving age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race (including colour, nationality, ethnic or national origin), religion and belief, sex, sexual orientation, education, language and socio-economic status.

Given this level of respect psychologists are obliged to explain the nature of the research to which participants are being asked to contribute, and to avoid any unfair, prejudiced or discriminatory practice, for example, in participant selection or in the content of the research itself.

For these reasons they accept that individuals may choose not to be involved

in research, or if they agree to participate they may subsequently wish that their data be withdrawn and destroyed. Under such circumstances researchers should seek to comply with requests subject to the requirements of data protection legislation. Where there are necessary time limits on data withdrawal, for example, up to a point at which data are aggregated, these limits should always be made clear to participants as part of the consenting process.

Psychologists respect the autonomy of individuals by making reasoned judgments about any actions in the course of their research that will have an impact on the autonomy of participants, even temporarily, and will always avoid any processes and procedures where any long-term impairment or perceived impairment of autonomy might result. A reasoned balance should be struck between protecting participants and recognising their agency and capacity.

Researchers will respect the privacy of individuals, and will normally ensure that individuals are not personally identifiable unless an individual so wishes, and then only with clear, unambiguous informed consent. Where a participant wishes to have their voice heard and their identity linked with this, researchers will endeavour to respect such a wish. Researchers will respect confidentiality and will ensure that information collected about individuals is appropriately de-identified and cannot be traced back to them by other parties, even if the participants themselves are not troubled by a potential loss of confidentiality.

This Principle recognises that persons connected with participants, such as partners, family members, colleagues may also be affected by research activities

In their research, as in all other professional dealings, psychologists will seek to ensure that people's rights are respected and protected. Participants' rights regarding intellectual property and ownership of data

in all forms of media must be respected. Researchers will actively confer these rights to participants throughout the duration of the research process.

2.2 SCIENTIFIC INTEGRITY

Value statement: Research should be designed, reviewed and conducted in a way that ensures its quality, integrity and contribution to the development of knowledge and understanding. Research that is judged within a research community to be poorly designed or conducted wastes resources and devalues the contribution of the participants. At worst it can lead to misleading information being spread and can have the potential to cause harm.

Ethics standards: Psychologists are committed to and are accountable for ensuring that the scientific and scholarly standards of their research are of sufficiently high quality and

robustness. Quality relates primarily to the scientific design of the research and the consideration of potential risks of harm and protocols for addressing such difficulties (should they arise). It is important that the aims of the research are as transparent as possible to ensure that it is clear what the research intends to achieve.

Judgements of scientific value must be appropriate within the context in which the research is being conducted (e.g. the status of the researcher – student, lecturer, senior researcher). See also Section 14 on student research.

2.3 SOCIAL RESPONSIBILITY

Value statement: The discipline of psychology, both as a science and a profession, exists within the context of human society. Accordingly, a shared collective duty for the welfare of human and non-human beings, both within the societies in which psychology researchers live and work, and beyond them, must be acknowledged by those conducting research.

Ethics standards: The aim of generating psychological knowledge should be to support beneficial outcomes. Such outcomes can be broadly defined as those that not only support and reflect respect for the dignity and integrity of persons (both individually and collectively) but also have potential to contribute to the 'common good'.

Accordingly, psychologists must be able to work in partnership with others (including professional colleagues, research participants, and other persons); be self-reflective; and be open to challenges that question the contributions of psychological knowledge to society. Psychology researchers need to be aware of their personal and professional responsibilities, to be alert to the possible consequences of unexpected as well as predicted outcomes of their work, and to acknowledge the often problematic nature of the interpretation of research findings. They should always work within the limits of their professional competence.

2.4 MAXIMISING BENEFIT AND MINIMISING HARM

Value statement: In accordance with Ethics Principle 3: Responsibility of the *Code of Ethics and Conduct*, Psychologists value their responsibilities to persons and peoples, to the general public, and to the profession and science of psychology, including the avoidance of harm and the prevention of misuse or abuse of their contribution to society

Ethics standards: Psychology researchers should seek to maximise the benefits of their work at all stages, from inception through to dissemination and application.

Psychologists should consider all research from the standpoint of the research participants and any other persons, groups or communities who may be potentially affected by the research, with the aim of maximising potential benefits and avoiding potential risks to psychological wellbeing, mental health, personal values, privacy or dignity.

Harm to research participants must be minimised. Where risks arise as an unavoidable and integral element of the research, robust risk assessment and management protocols should be developed and complied with. Normally, the risk of harm should be no greater than that encountered in ordinary life, i.e. people should not be exposed to risks greater than or additional to those to which they are exposed in their

normal lifestyles. Where a tension arises between the legitimate needs of research and the avoidance of risk, reasoned judgement should be applied, based on the principles in this *Code of Human Research Ethics*.

If unavoidable additional risks are present, researchers should assess these risks for their probability and severity, and put in place measures to mitigate, minimise and manage such risks.

Psychologists need to be sensitive to the potential impact of their involvement with participants, for example, to the possibility of unwittingly causing distress or to creating self-doubt. A difference in power typically exists between researchers and participants, even if researchers seek to minimise it. Sensitivity is, therefore, essential, and caution is always necessary. In conjunction with the previous section of this *Code of Human Research Ethics* it may be that researchers will need to consider the costs to the individual participant versus potential societal benefits. This is a difficult balance to strike and should be arrived at by careful and explicit analysis, and where appropriate, wider consultation with experienced colleagues, the relevant REC or user group(s).

Further discussion of risk in psychological research can be found in the following section.

3. Risk

Risk can be defined as the potential physical or psychological harm, discomfort or stress to human participants that a research project may generate. This is an important consideration in psychological research, where there is a wide range of potential risks. These include risks to the participant's self-esteem, personal social status, privacy, personal values and beliefs, and personal relationships, as well as the adverse effects of the disclosure of illegal, sexual or deviant behaviour. Research that carries no physical risk can nevertheless be disruptive and damaging to research participants (both as individuals or whole communities/categories of people).

It can be difficult to determine all potential risks at the outset of a piece of research. However, researchers should endeavour to identify and assess all possible risks and develop protocols for risk management as an integral part of the design of the project, and ensure that appropriate levels of ethics review are sought.

The following research would normally be considered as involving more than minimal risk:

Research involving vulnerable groups (such as children aged under 16; those lacking mental capacity; or individuals in a dependent or unequal relationship, or who have prior experience of psychological or physical harm or adversity in its broadest sense);

Research involving potentially sensitive topics (such as participants' sexual behaviour; their legal or political behaviour; their experience of violence; their gender or ethnic status);

Research involving a significant and necessary element of deception;

Research involving access to records of personal or confidential information (including genetic or other biological information);

Research that might open access to potentially sensitive data through third parties;

Research that could induce psychological stress, anxiety or humiliation or cause more than minimal pain (e.g. repetitive or prolonged testing);

Research involving invasive interventions (such as the administration of drugs or other substances, vigorous physical exercise or techniques such as hypnosis) that would not usually be encountered during everyday life;

Research that may have an adverse impact on employment or social standing (e.g. discussion of an employer, discussion of commercially sensitive information);

Research that may lead to 'labelling' either by the researcher (e.g. categorisation) or by the participant (e.g. 'I am stupid', 'I am not normal');

Research that involves the collection of human tissue, blood or other biological samples.

Some research may pose risks to participants in a way that is legitimate in the context of that research and its outcomes. For example, research to reveal and critique fundamental economic, political or cultural disadvantage and exploitation may involve elements of risk. Further, some research may be considered legitimate if the longer-term gains outweigh the short-term immediate risks to participants (provided that these risks are minimal and neither have lasting effects nor induce prolonged personal discomfort). In instances where an element of risk is an unavoidable

element of the research design, a detailed case outlining the cost-benefit analysis and the risk management protocol should be submitted to the REC.

Risk analysis should not only be confined to considering the interests of the primary participants, though these are paramount, but should also consider the interests of any other stakeholders. Where appropriate, the use of risk analysis tools may offer a useful way of identifying, quantifying and managing potential hazards.

4. Valid consent

Researchers should ensure that every person from whom data are gathered for the purposes of research consents freely and voluntarily to participation, having been given sufficient information to enable them to make an informed choice. They should be free during the data gathering phase to withdraw or modify their consent and to ask for the destruction of all or part of the data that they have contributed within agreed and consented limits.

The way in which consent is sought from people to participate in or otherwise contribute data for research should be appropriate to the research topic and design, and to the ultimate outputs and uses of the analyses. It should recognise in particular the wide variety of data types, collection and analysis methods, and the range of people's possible responses and sensitivities. The principle of proportionality should apply, such that the procedures for consent are proportional to the nature of participation and the risks involved.

For example, for data from existing datasets where consent was properly gained in the initial collection and this consent covers the uses of data proposed, no further consent will normally be needed. For de-identified-at-source, non-sensitive data, consent may usually be considered to have been given by the act of participation or by ticking a box, for example. Nevertheless, the risks involved in some research where data are de-identified at the point of collection, for example, web-based research on sensitive topics such as sexual behaviours, will require carefully prepared

prior information and clear consent processes. The open research agenda is driving increased requirements for demonstrating the integrity of research and making research datasets publicly available in a data repository. This is often a requirement of editors and publishers, and participant information should be prepared with this in mind.

When research involves the collection of identity capturing data on sensitive topics, using video or audio recording, or other media and methodologies where an individual may be identifiable, such as diary studies, it is important to consider additional informed consent procedures. These procedures need to be related to both the nature of the data collected and the ultimate use of the data. Separate informed consent agreements for data collection and the dissemination of the study's results may be required.

Researchers should ensure that the protocol they follow for seeking, taking and recording consent is appropriate to local customs, legal frameworks and cultural expectations, and to the nature of the research and its topic, while adhering to the principle of validity. While written consent, as described below, will be the usual approach, other methods, such as audio-recorded verbal consent or implied consent (for example, in choosing to input responses to an anonymous online survey on a non-sensitive subject), may be preferable if based on a careful consideration of the research context. It is always important that consent should be documented in an auditable record.

4.1 INFORMING PARTICIPANTS

Consent is not valid unless it is given from an informed perspective. Giving potential participants necessary and sufficient information about the research in an understandable form is crucial to giving them an adequate basis for deciding whether or not participate. This requires careful thought

about the most appropriate means to use, which might include oral, pictorial, audio, or video media as well as or instead of a textual information sheet. Format is also important; it can be paper but digital formats are also common. Whatever the chosen medium, information must be accessible and portable.

It is important that people are addressed politely, respectfully and, where appropriate, compassionately. It is recommended that at least one pilot test of the processes for informing and debriefing participants be carried out with a person naïve to the research and with a literacy/understanding level at the lower end of the range expected in the planned research sample. In certain circumstances the aims of the research may be compromised by giving full information prior to data collection. In such cases, it should be made clear that this is the case in the participant information and the means by which the withheld information will be given at the conclusion of data collection should be specified. The amount of information withheld and the delay in disclosing the withheld information should be kept to the absolute minimum necessary.

The information given to potential participants for them to keep should normally offer a clear statement of all those aspects of the research that are relevant for their decision about whether or not to agree to participation. The following list offers a series of headings for consideration. Not all of these will be relevant in specific cases.

The aim(s) of the project.

The type(s) of data to be collected.

The method(s) of collecting data.

Confidentiality and anonymity conditions associated with the data including any exceptions to confidentiality, for example, with respect to potential disclosures.

Compliance with the Data Protection Act (2018).

The time commitment expected from participants.

The right to decline to offer any particular information requested by the researcher.

The opportunity to withdraw from the study at any time with no adverse consequences.

The opportunity to have any supplied data destroyed on request (up to a specified date).

Details of any risks associated with participation.

If appropriate, a statement that recompense for out of pocket expenses and payment for time and inconvenience associated with participation will be given, normally without specifying the amount or nature of such payment beyond the reimbursement of incurred expenses such as travel costs.

The name and contact details of the Principal Investigator.

The name and contact details of another person who can receive enquiries about any matters which cannot be satisfactorily resolved with the Principal Investigator.

Details of any insurance indemnity for the research.

Any debriefing that is planned.

How the data will be owned, stored and used, and future uses including in open datasets.

A privacy notice.

Planned outcomes and potential benefits of the research.

How the results of the research will be made available to participants.

Which of these headings are appropriate, and the extent of information given under each, will depend on the nature of the research. The language used in giving information should be clear and accessible to all potential participants, using short words and sentences in the active voice and avoiding the use of technical terms.

4.2 CONSENT AND RISK

A prior assessment of potential risks should inform the preparation of the information to be given to potential participants and the procedures for seeking consent. This assessment should be used to determine the appropriate form of consent and the nature of any risk management required. When in exceptional circumstances harm, unusual

Sufficient time should be given for potential participants to absorb and consider the information given about the research and what is expected of their participation before they are asked to make a decision regarding participation. There should also be adequate opportunity given for potential participants to ask questions and have them answered.

discomfort, or other negative consequences for the individual's future life might occur, the investigator must inform the participants clearly of these additional risks prior to consent. For all research where risks are present, secure liability insurance should be in place to adequately cover the levels of possible harm identified in the risk analysis.

4.3 RISK AND PROPORTIONALITY

Psychological research with humans varies greatly in terms of the risk levels and ethical issues involved. Simple online research into non-sensitive topics where no personal identifiable data are gathered could be seen as setting a lower boundary of risk and ethics concern, while research into personally challenging life events would be closer to the upper limit.

There can be no easy 'one size fits all' research ethics protocol or review process to suit every proposed research project. Instead, there is a need to employ risk assessment processes that can fully identify the range of anticipated risks and develop appropriate management and mitigation.

Risk assessment is often seen as a five-stage process:

1. Identify the risks
2. Establish the potential harms and persons potentially affected
3. Evaluate the scale of risks and develop control measures
4. Document the findings in a protocol
5. Assess effectiveness by considering a) the magnitude of the potential harms and b) the likelihood of them happening, then modify as necessary

Where a researcher follows such a process, Stage 4 will result in a protocol that can provide a Research Ethics Committee with a basis for deciding the nature of the review. This should be proportionate and might range from simple self-assessment using a checklist to full review by committee.

Stage 5 will help to ensure that previously unidentified risks or inaccurate judgements of scale of risk are properly managed during the research itself. Best practice is to inform the REC if such changes arise so that protocol modifications can be reviewed.

Participation in some research can confer benefit to individuals, wider society and the academic community. Risk should always be evaluated in relation to wider benefit; however, the interests of individuals should never be subordinated to those of wider society.

4.4 ASSURING VALID CONSENT

The consent of participants in research, whatever their age or competence, should always be sought, by means appropriate to their personal characteristics. Special safeguards need to be in place for research with vulnerable populations and persons with specific vulnerabilities. Vulnerable populations include children, persons lacking capacity, those in a dependent or unequal relationship, people with learning or communication difficulties, people in care, people in custody or on probation, people who have suffered physical or psychological trauma and people engaged in illegal activities, such as drug abuse. Researchers should be aware of the risk of stigmatisation and ensure that this Code's Principle of Respect for the Autonomy and Dignity of Persons is fully upheld. Psychologists should ensure that participants from vulnerable populations where understanding be more difficult are given ample opportunity to understand the nature, purpose and anticipated outcomes of any research participation, so that they may give consent to the extent that their capabilities allow. Methods that maximise the ability of vulnerable persons to give informed consent and that respect their agency should be used whenever possible.

Researchers should ensure that they are aware of the provisions of the Mental Capacity Act 2005 and/or other legislation applicable in the location(s) of the research and any

requirements with respect to ethics review of research, the provision of adequate liability cover, and the special requirements for gaining valid consent. Researchers should also be aware of and respond to the need for appropriate criminal records disclosures and clearances when their research involves contact with vulnerable people.

Where children are concerned, there is no one-size-fits-all approach to putting in place ethically sound protocols for ensuring that they participate freely and voluntarily in research with an appropriate understanding of what their participation involves. Much depends on the ages of the children and their developmental levels, as well as the specific demands of research projects. Best practice is for researchers to engage in early planning of their consent procedures, and piloting where appropriate, to ensure that the target population characteristics have been well understood and have informed the planning. Of equal importance is the need to be clear who else are stakeholders in the consenting process, for example, parents and teachers, to name those most frequently concerned. Already in the opening sentence above some of the key considerations for researchers have been alluded to: respecting children's autonomy and giving them enough and appropriate information to inform their choices.

4.5 AGE

There is uncertainty as to the age at which a young person moves from the status of 'child' to that of 'adult'. This is significant for researchers because a decision must be made whether parental/guardian consent for

research is needed in addition to consent from the participant. The UK age of majority is 18 years, at which point a person becomes legally an adult. However, the Mental Capacity Act defines 'adult' as a person aged 16 years or

older, while many RECs in the NHS and other organisations accept what has become known as ‘Gillick’ or ‘Frazer’ competence; that if a young person of whatever age has capacity to consent, they can do so without parental consent in addition. On balance, the age of 16 should be acceptable for sole consent on the part of the young person for low-risk research, but if in doubt parental consent should be sought as well.

It should be noted that minors under the age of 18 have a legal right to safeguarding. Thus a researcher might be able to legitimately gain the consent of a 16-year-old but they are likely to still have safeguarding duties for persons under the age of 18.

In common with best practice when working with adults, the default position should be to assume that the target children for participation will be capable of making an informed decision as to whether or not to participate, provided they are given adequate information in a form that they can understand and that they do not feel in any way coerced into consenting.

Similarly, children’s rights as owners of their own data are no different to those of adults, so equal respect should be given to their views and wishes regarding data management, and data destruction where they so wish. Children are unlikely to have a good understanding of the implications of data storage and sharing, so these will need to be explained to them in accessible terms.

Ensuring that children are under no pressure to participate demands careful consideration of the power relations that almost inevitably exist between adults and children. Power is exerted by the context as well, for example, the school or early years setting is one in which a degree of compliance with adult direction is required and enforced, either subtly and kindly, or more directly. Thus, seeking consent from a child in such settings will already result in some degree of influence, even if does not meet the fuzzy threshold beyond which coercion would be recognised.

Seeking participation consent from a child is a social negotiation, not just a paper exercise. In recognition of this, careful preparation of consent procedures can include, for example, questions to which a child can be expected to say no, and encouraged by the person seeking consent making it clear that it is fine to say ‘no’ and that the child is free to say ‘no’ also to participation, and to cease participation, to ‘withdraw’, at any time. The crucial element here is ‘no consequences to saying no’, and this is not always easy to convey clearly to a child.

Children are used to being in inferior power relations with adults, it is their default expectation, so a researcher will have to make special efforts to establish the different relation that positions the child as a free agent.

With few exceptions, it is not only the child’s decision regarding participation. Typically, it will be necessary to seek the consent of one or both parents or other person(s) with a legal responsibility to protect the child’s best interests. If a child indicates that they do not wish to participate or that they wish to cease participation, best practice is to see the child’s wishes as trumping any counter wish on the part of the parent(s) or other responsible person(s) for the child’s participation to commence or continue.

For school-based research, where the research activity is identical with or very similar to standard curriculum practice, the consent of the head teacher may be sufficient in addition to child consent, as long as parents are informed of the research and it is an expectation in the school and among parents that such research may take place. The process in these cases needs to be carefully vetted by the head teacher.

Respecting autonomy also means being sensitive to non-verbal signs that a child is unwilling to consent or to continue participation. Signs to watch out for could include looking away, not making eye contact, becoming silent or monosyllabic in replies, withdrawing into self or nervous fidgeting.

4.6 INFORMING CONSENT

The developmental age of a child, particularly in respect of literacy level as well as reasoning and decision-making capacities, is a crucial consideration when planning how best to inform the child about the research, so that their consent decision is validly informed. The information given must be sufficiently comprehensible and clear that the child knows what they are agreeing to. Best practice is to check texts and scripts for age-appropriate literacy level and to pilot with the target age group.

For younger children, the use of pictograms or other forms of graphic communication is worth considering. Similarly, the response mode to questions seeking agreement could make use of smiley/sad face icons to be circled rather than tick boxes.

Any paper-based consenting process should normally be supplemented by a scripted verbal introduction and a clear invitation to the child to ask any questions that they want to about what participation would entail.

Provision of information does not have to be paper-based. Researchers should consider the use of other media such as short films and animations which can be provided in digital formats. In some cases a simple oral explanation is sufficient. It should always be borne in mind that a signature on a consent form is not in itself consent – it is a record of it. A similar record could be made elsewhere including the researcher's field notes. The main concern is that, unlike adults, a single information text will not be suitable for children of all ages; it is likely to be necessary to have two or three versions covering appropriate age ranges.

4.7 ASSENT

While written or verbal consent is seen as the ideal form of assuring valid agreement with adults to participate in research, for children, non-verbal channels are very salient in how they express their feelings. Pressures of power differential or context can induce children to agree verbally with things that they might in fact not be happy with.

Recognising that consent, or a lack of consent, can be expressed in other ways than through language leads to the important concept of assent. This requires the researcher to

monitor a child's non-verbal behaviour and to be sensitive for signs that the child is not comfortable with the situation, with requests that are being made or with tasks that they are presented with. Signs of lack of assent can be many, but the most obvious are becoming withdrawn and quiet, perhaps taking longer than expected to answer questions or follow prompts, breaking and avoiding eye-contact, 'closed-in' body posture or looking towards exits or out of windows. Such signals should be seen as equally important as signatures on a consent form.

4.8 RESEARCH IN SCHOOLS OR OTHER INSTITUTIONS

In relation to the gaining of consent from children and young people for participation in research in school or other institutional settings, where the research procedures are judged by a senior member of staff or other appropriate professional within the institution to fall within the range of usual curriculum or other institutional activities, and where a

risk assessment has identified no significant risks, consent from the participants and the granting of approval and access from a senior member of school staff legally responsible for such approval can be considered sufficient. However, best practice is to inform parents/guardians that the research will take place and offer the opportunity to opt-out their children's

participation. Where these criteria are not met, it will be a matter of judgement as to the extent to which the difference between these criteria and the data gathering activities of the specific project warrants the seeking of opt-in parental consent from children under 16 years of age and young people of limited competence.

4.9 ADULTS LACKING CAPACITY

A person must be assumed to have capacity to consent to participation in research unless it is established that they lack capacity. If there is any question that a participant lacks capacity to consent, there must be a test of capacity. Assessing capacity should be done following the guidance on page 10 of the BPS guidance document *What makes a good assessment of capacity?*

If testing shows that a potential participant does lack capacity and there are compelling

When research is being conducted with detained persons, particular care should be taken over informed consent, paying attention to the special circumstances which may affect the person's ability to give free informed consent.

grounds for recruiting them, such as it would not be possible to conduct the research without their inclusion, then an application must be made to a Health Research Authority research ethics committee via the Integrated Research Application System. The BPS guidance document *Conducting research with people not having the capacity to consent* should be consulted and the advice given there followed.

4.10 INDIVIDUALS WHO HAVE EXPERIENCED PSYCHOLOGICAL AND PHYSICAL HARM AND OR CUMULATIVE ADVERSITY

Where research is to examine issues and population groups who have or are anticipated to have experienced significant prior distress, appropriate protection measures need to be put in place. Examples of such individuals and groups will include survivors of interpersonal abuse, survivors of natural disaster, refugees.

Safeguarding the researcher: Researchers will need to evidence to the REC that they have considered and put in place appropriate measures to address their own psychological and physical safety and wellbeing.

Safeguarding the participant: Researchers will need to evidence to the REC that they have sufficient competence (see above) to work with the issues and population group.

Safeguarding the wider stakeholder community: researchers will need to evidence to the REC that they have considered and put in place appropriate measures to address the impact of their involvement on the participants' wider community. Researchers will need to demonstrate, for example, how they will work with gatekeepers of the local community to identify and mitigate any actual or perceived adverse impact.

4.11 DOCUMENTING CONSENT

Consent, whether in a verbal recording, electronic or hard copy form, should include an explicit statement confirming that information about the research has been given to the participant and has been understood. Clarity about future uses of the data is critical, for example, it is important that participants do not misunderstand any collection of health-related data from them as constituting any form of medical screening. Such misapprehensions might lead them to be less vigilant in relation to seeking medical attention for risks or symptoms of illness.

Normally, where written consent is taken, two copies of a consent form should be signed by the researcher and the consenting participant, and/or their parent/guardian. One copy should be retained by the participant and the other stored by the researcher. The copy retained by the participant should give contact details of a person who may be contacted in the case of any queries arising. For certain types of research, for example, where there are identifiable risks, it will also be appropriate for the consent to be witnessed and signed by an independent third

party. All records of consent, including audio-recordings, should be stored in the same secure conditions as research data, with due regard to the confidentiality and anonymity protocols of the research which will often involve the storage of personal identity data in a location separate from the linked data.

Investigators should realise that they are often in a position of real or perceived authority or influence over participants. For example, they may be gathering data from their students, employees or clients, from prisoners or from other detained or vulnerable people. This relationship must not be allowed to exert pressure on people to take part in or remain in an investigation and the potential for a power relationship to bias the data should be considered. Similarly, where people in positions of power over potential participants, for example, school teachers, managers or prison staff, serve as gatekeepers or recruiters for research, the potential for coercion arising from the power relationships should be recognised and steps taken to avoid it

4.12 REIMBURSEMENT, PAYMENT, INCENTIVES AND COERCION

These four constructs lie along a continuum of increasing ethical concern, with coercion as an unacceptable contravention of the core CHRE principle of respect for the autonomy of persons.

Incentives, however, while they still seek to encourage persons to participate in research, can be ethically acceptable so long as they are not so large that they run the risk of compromising a persons' freely made decisions to participate, which would violate the principle of respect for autonomy and become coercion. Incentives should be proportionate to the extent of burden of participation but should never be associated with the degree of any risk. Normally incentives should be at the same level for all participants in a project.

However, there may be circumstances, such as a research design where purposive stratified sampling is essential, when varying incentives to ensure adequate representation of specific groups can be ethically justified.

Reimbursing expenses incurred in participating in research, such as travel, is normally ethically required and is common practice. Asking persons to participate at their own expense is clearly unreasonable. Payment should be offered (while it may not always be accepted) where participants are giving up substantial amounts of their time. There is an argument that giving time to activities that can potentially benefit science and human wellbeing should be seen as a valid citizenship expectation. Of course not all research can make such a

claim. Payment for time given to research participation is ethically problematic because deciding on levels of payment and whether these should relate to persons' earning capacities is challenging and may be seen as discriminatory. If it is felt appropriate to pay for time, a standard across-the-board token level of payment (for example, at minimum wage level) is a good starting point for consideration. In some circumstances, such as elite interviews, it may be necessary to justify higher levels of payment, but this should be the exception rather than the rule. It is accepted that not all research is sufficiently funded to reimburse expenses and pay for time. In these circumstances it is normal practice to make the position clear at the time of recruitment; many potential participants are altruistically motivated. Furthermore the need for reimbursement can be significantly reduced by considering the timing and location of the research.

Token levels of payment for research participation are not seen by HM Revenue and Customs as income for tax purposes. Alternatives to direct monetary recompense can take the form of vouchers to spend in specific retailers, small gifts (food or drink may have health and safety issues), or 'certificates of participation'. Gifts, certificates, books, stickers or T-shirts with appropriate printed logos and text are especially appropriate for children.

Some researchers have made use of prize draws as an incentive, but this can be seen as objectionable by virtue of endorsing gambling. If a lottery approach is used, the prize(s) should be modest in value, again to avoid risk of coercion. The use of prize draws raises a further ethical issue: it is necessary to collect and store contact details which raises data protection issues. Some research can be conducted entirely anonymously; collecting contact details for the sole purpose of entry in a prize draw is ethically questionable.

4.13 REWARDS

Some psychological research involves the use of rewards as an intrinsic aspect of the chosen method. This sort of research is often on topics such as the nature of competition or, conversely cooperation. Research of this nature is often found in the developing field of artificial intelligence in the context of neuroscience; it might include the use

of online gaming. There is often a degree of deception involved; whilst participants might be led to believe that they are being differentially rewarded it is normal to make the same payment to all participants on completion of the experiment. Suitable debriefing will be required.

4.14 RENEWAL OF CONSENT

Where the research requires a substantial commitment of time or repeated data collection sessions, such as in longitudinal studies, it will often be appropriate to seek renewed consent from participants. This also recognises that consent should be an ongoing process and that a fuller appreciation of the research and the nature of participation will often become more apparent to participants during the course of their involvement with the research.

Participants should be given information as to whom they may contact in the event of any issues arising in the course of the research that cannot be resolved with members of the project team. Such a contact should be both independent of the project team and also in a position to take appropriate action if issues are raised by participants.

5. Confidentiality

Subject to the requirements of legislation, including the Data Protection Act (2018), information obtained from and about a participant during an investigation is confidential unless otherwise agreed in advance. Investigators who are put under pressure to disclose confidential information should draw this point to the attention of those exerting such pressure. Participants in psychological research have a right to expect that information they provide will be treated confidentially and, if published, will not be identifiable as theirs. In the event that confidentiality and/or anonymity cannot be guaranteed, the participant must be warned of this in advance of agreeing to participate.

The duty of confidentiality is not absolute in law and may in exceptional circumstances be overridden by more compelling duties such as the duty to protect individuals from harm or alerting authorities to evidence of terrorist activity. Where a significant risk of such issues arising is identified in the risk assessment, specific procedures to be followed should be specified in the protocol. Further details on matters concerning confidentiality will be found in the Society's *Code of Ethics and Conduct and Professional Practice Guidelines*.

6. Giving advice

In some kinds of investigation the giving of advice is ethical if this forms an intrinsic part of the research, is agreed with the participant and has been subject to ethics review in advance. In other circumstances, however, a researcher may obtain evidence suggesting the existence of psychological or physical problems of which a participant may appear to be unaware. In such a case, the investigator has a responsibility to discuss this with the participant if the investigator believes that by not doing so the participant's future wellbeing may be endangered. Where there is an identified risk of such evidence emerging it is

good practice to prepare a protocol in advance and establish an appropriate referral route.

If, in the normal course of psychological research, or as a result of problems detected as above, a participant asks for advice about educational, personality, behavioural or health issues, caution should be exercised. If the issue is serious and the investigator is not competent to offer assistance, signposting to appropriate professional advice and or services is recommended. Further details on the giving of advice will be found in the Society's *Code of Ethics and Conduct*.

7. Deception

Deception or covert collection of data should only take place where it is essential to achieve the research results required, where there are no alternatives, where the research objective has strong scientific merit and where there is an appropriate risk management and harm alleviation strategy.

The experience of deception in psychological research may have the potential to cause distress and harm and can make the recipients cynical about the activities and attitudes of psychologists. However, since there are very many psychological processes that are modifiable by individuals if they are aware that they are being studied, stating the research focus to a participant in advance of the collection of data would make some psychological research impossible. There is a difference between withholding some of the details of the hypothesis under test and deliberately falsely informing the participants of the purpose of the research, especially if the information given implies a more benign topic of study than is in fact the case. This *Code of Human Research Ethics* expects all psychologists to seek to supply as full information as possible to those taking part in their research, recognising that providing all of that information at the start of a person's participation may not be possible for methodological reasons. If the reaction of participants when deception is

revealed later in their participation is likely to lead to discomfort, anger or objections from the participants then the deception is inappropriate. If a proposed research study involves deception, it should be designed in such a way that it protects the dignity and autonomy of the participants.

Where an essential element of the research design would be compromised by full disclosure to participants, the withholding of information should be specified in the project protocol that is subjected to ethics review and explicit procedures should be stated to prevent any potential harm arising from such withholding.

Studies based on observation in natural settings must respect the privacy and psychological wellbeing of the individuals studied. Unless those observed give their consent to being observed, observational research is only acceptable in public situations where those observed would expect to be observed by strangers. Additionally, particular account should be taken of local cultural values and of the possibility of intruding upon the privacy of individuals who, even while in a normally public space, may believe they are unobserved.

See also the relevant sections of the *Code of Ethics and Conduct* and the Society's guidance on web-based research.

8. Research with individuals in a dependent or unequal relationship

Researchers should be particularly diligent in establishing the valid consent of any person who is in a dependent or unequal relationship to them (e.g. student or client) because of the increased risk of consent being given under

perceived coercion or obligation. Researchers should ensure that appropriate consents are obtained from any gatekeepers to participants, for example, school principals, parents or legal guardians.

8.1 UNDERGRADUATE STUDENTS' PARTICIPATION IN RESEARCH

Undergraduate participation in psychological experiments is not required for Society accreditation. It has to be recognised, however, that most psychological research involves human participants and that courses in psychology need to acquaint students with appropriate methods for carrying out such research. Participation by students in psychological research provides them with valuable experience, not just with methodology but also with the ethics problems that can arise when carrying out experiments and other forms of research. Indeed, it can be argued that it is unethical for psychology students or graduates to carry out research with others unless they have been willing to participate and have had experience of participation in such research themselves. As a consequence, this forms a normal part of undergraduate training. Students taking undergraduate

laboratory classes in psychology, for example, typically recruit each other as participants, as well as recruiting participants other than psychology students for their research.

This *Code of Human Research Ethics* requires that there should be valid consent and no coercion in the recruitment of student participants. Given the non-invasive nature of most psychological research this generally does not present problems. However, in cases where problems with particular forms of research do arise, it is recommended that participants should be given alternatives so that there is no coercion to participate in any particular study. It is also recommended that, where research participation is a course requirement, this be clearly stated in course handbooks or other advertising material, enabling prospective students who do not wish to take part in research to opt for a different course.

9. Research in the NHS and social care settings

Most psychological research involving human participants is ethically reviewed by university RECs but research involving NHS patients, their carers or relatives and clients of public social care services must be reviewed externally. Ethics review is undertaken by NHS RECs or the national Social Care Research Ethics Committee and application is made via the IRAS (Integrated Research Application Service) system. The ethics service is provided by the Health Research Authority (HRA), which provides extensive guidance on its website. If patients, clients, carers/relatives are to be recruited in their capacities as such via public services, in nearly all cases external review will be required. There are some exceptions to this general rule, so it is worth checking

whether it is necessary; the HRA provides advice. In addition to this policy requirement some research has to be submitted to the HRA on legal grounds even if it does not involve this group of potential participants. The examples which are most likely to be relevant to psychologists are research involving adults lacking capacity and some research involving the storage of human tissue. Human tissue is basically any material including cells, so if a psychologist were to take a buccal smear to measure cortisol in a study involving understanding stress, they would have collected human tissue and it might be necessary to seek HRA ethics review. Further advice is provided by the HRA.

10. Debriefing

As outlined in the *Code of Ethics and Conduct* (Section 3.4), when the research data gathering is completed, especially where any deception or withholding of information has taken place, it is important to provide an appropriate debriefing for participants. In some circumstances, the verbal description of the nature of the investigation will not be sufficient to eliminate all possibility of harmful after-

effects. For example, following an experiment in which negative mood was induced, it would be ethical to induce a happy mood state before the participant leaves the experimental setting.

It may be the case that some participants do not take up the offer of debriefing or other information, nevertheless this should be offered when appropriate.

11. Positive value of engagement with ethics review

Too often, 'ethics' has been seen by researchers as focused on the formal review of an ethics protocol by a Research Ethics Committee, as a last hurdle to be jumped and a hindrance to progress with the research. This perception is not helped by narrow institutional views that the formal review is the main, and sometimes only, way that ethics standards are maintained or 'policed'. However, it is increasingly the case that universities and other research organisations are recognising that ethics is an end-to-end process in research – ethics issues pervade all stages from inception through to dissemination and application. In part this increased awareness has arisen because of growing concerns around research integrity, but also because of advances in the field of research ethics, notably the greater interest in virtue ethics, which lends support to the view of research ethics as pervasive given its extension to the continuing moral conduct of the researcher rather than a narrow focus on the protocol. Funding bodies are also tending to place more stress on the ethics of proposed research, hence researchers should be seeing a concern for ethics as an integral part of the whole research process.

Nevertheless, the formal pre-emptive REC review does play an important role in establishing the groundwork for a research project. External scrutiny by an independent panel offers the opportunity for formative input to help researchers avoid risks and maximise benefits. An ideal situation is where the institution sees the need for additional facilitation before and also after the formal review.

It is important to note that, in common with NHS RECs, most university RECs give opinions rather than approvals. A favourable ethical opinion is a necessary but not sufficient condition for research to proceed; approval to proceed can only be given once all matters of research governance have been addressed and agreed. Approval to proceed is a governance matter and the process for giving approval will depend on the specific governance structure of the research organisation.

12. Independent researchers seeking ethics review

Where a researcher is working independently from any organisation that has an established, formal ethics review process it can be difficult to know how to proceed if the researcher is seeking a review for their project. It is a requirement of many academic journals that an author reporting human research attests to a favourable opinion having been given following a review of the ethics protocol for their research. There is also a moral argument that any human research project that raises ethics issues should be independently reviewed and that the research data collection is not started until a favourable opinion is received.

Some university research ethics committees are open to receiving applications for review from researchers who are not affiliated in any way with the university and are prepared in some cases to give an informal or formal response, either by chair's action or through a process that involves other committee members, ranging up to full review by the same process as for university-linked research. Contact should be made with the secretary of a university committee to explore what options are available. It is possible that more than one university would need to be contacted before an acceptable agreement can be reached. It should be noted that some universities will charge for this service. Achieving access to ethics review by a university committee could

be facilitated by finding an academic member of a university who is prepared to join the research as a co-investigator. Other universities will only offer this service to those working or studying within them.

Some larger charities and commercial organisations that carry out research may also have research ethics committees that might consider reviewing project protocols that fall within their own areas of interest. Here also, seeking an engagement in the project by a researcher within the charity or organisation might facilitate access to review.

There is a small number of independent research ethics committees. These will charge for their services but often on a not-for-profit basis.

Where it is not possible to find a means of gaining a formal review, completing the sample ethics review application proforma in this Code will help to ensure that relevant ethics issues are considered and that there is a documented protocol for the research project.

Minimal risk projects may be considered to not require a formal ethics review. However, establishing that a particular project is indeed minimal risk depends on having carried out a thorough risk assessment.

13. Principles of best practice in ethics review

This section of the *Code of Human Research Ethics* sets out principles for ethics review outside of the Health Research Authority Research Ethics Service system because the ethical conduct of research is concerned with broader issues than simply the conduct of research with participants; it includes the necessary element of independent review of

ethics protocols. In many situations, such as in university psychology departments, there will be a local responsibility to ensure that ethics review complies with current best practice and with the expectations and requirements of sponsors, funding bodies and other stakeholders.

13.1 THE PRINCIPLES

INDEPENDENCE

The ethics review process should be independent of the research itself.

Value statement: This principle highlights the need to avoid conflicts of interest between researchers and those reviewing the ethics protocol, and between reviewers and organisational governance structures. It is linked with the fourth principle, which requires recognition of the responsibility of RECs and the need to formulate this clearly. It also recognises the need for external

membership of RECs (sometimes described as 'lay' membership). It is important to recognise the distinction between the review of research ethics and the subsequent governance of research, which will include approval once a favourable opinion has been given, since independence is a core principle in the review process while different considerations may apply in the ongoing governance of research once approved following an ethics review process.

COMPETENCE

The ethics review process should be conducted by a competent body.

Value statement: This second principle addresses the need for research protocols

to be properly evaluated by reviewers with appropriate expertise and highlights the need for careful consideration of the range of membership and ethics specific training of RECs.

FACILITATION

The review process should facilitate the understanding and implementation of ethical practices.

Value statement: In addition to the core duty of responding to applications for ethics review

with constructive and timely responses, this principle invokes a responsibility to educate, inform and support researchers in the development of their research protocols. RECs should be responsive and avoid delaying valuable research.

TRANSPARENCY AND ACCOUNTABILITY

The review process should be accountable and open to scrutiny.

Value statement: RECs need to recognise their responsibilities and to be appropriately located

within organisational structures that give transparency to the REC operation and to the procedures to maintain and review standards.

13.2 THE ROLE OF A RESEARCH ETHICS COMMITTEE (REC)

A REC is normally responsible for:

Reviewing research involving human participants conducted by individuals employed within or by that institution;

Ensuring that ethics review is independent, competent and timely;

Protecting the dignity, rights and welfare of research participants;

Considering the safety of the researcher(s);

Considering the legitimate interests of other stakeholders;

Making informed judgements of the scientific merit of proposals; and

Making informed recommendations to the researcher if the proposal is found to be wanting in some respect.

13.3 THE CONSTITUTION OF A RESEARCH ETHICS COMMITTEE

A REC should normally:

Be multidisciplinary;

Include both men and women;

Include at least one appropriately trained external member with no affiliation with the department, university or research institution;

Be comprised of members with a broad experience of and expertise in the areas of research regularly reviewed by the REC; and must have the confidence and esteem of the research community;

Include least one member with specialist knowledge in ethics;

Include individuals who reflect the ethnic diversity of the local community; for example users of specialist health, education or social services; individuals with experience of professional care or counselling where these are the focus of research activities; and individuals with specific methodological expertise relevant to the research they review; and

Be constituted so that conflicts of interest are avoided.

This would typically mean that a REC comprises at least seven members.

13.4 TRAINING AND DEVELOPMENT OF RESEARCH ETHICS COMMITTEE MEMBERS

The success of a REC relies largely on the degree to which research organisations are able to build appropriate structures and create a culture that recognises the central place that ethics review occupies in good research practice. Ethics training plays a central role in this process; such training should be on-going and become an integral part of research practice.

Successful RECs require agreed minimum standards of training and competence, which may be achieved through programmes at institutional, faculty, departmental or research centre/unit level. The aim of the training should be to provide individuals with confidence in their abilities to conduct thorough and consistent ethics scrutiny of psychological research.

13.5 MONITORING

All research organisations should establish appropriate governance procedures to monitor the conduct of research which has received ethics approval until it is completed, and to ensure continuing review where the research design anticipates possible changes over time that might need to be addressed. Monitoring should be proportionate to the nature and degree of risk associated with the research. It should include consideration of best-practice procedures for the secure holding and preservation (or destruction where appropriate) of the data, including making data available

in accordance with open data agendas and requirements.

Where a REC considers that a monitoring report raises significant concerns about the ethical conduct of the study, it should request a full and detailed account of the research for full ethics review.

Where it is judged that a study is being conducted in a way that is unethical, it should consider the withdrawal of its approval and require that the research should be suspended or discontinued.

13.6 DEVOLVED ETHICS REVIEW

In many organisations ethics review of individual protocols is devolved to departmental level committees. In the case of psychological research this will often mean that a department will have a devolved responsibility for reviewing protocols originating within the department. To avoid conflicts of interest and to assure best practice in ethics review, it is essential that responsibility for the conduct of ethics review should reside with a properly constituted body that has clear independence. In some cases, research may be judged to be outside the remit of ethical review; it is important that such research is regularly audited so that research that requires scrutiny is not inappropriately ignored.

Although much undergraduate research is controlled in order to be low or minimal risk, and often involves pre-planned research designs in order to ensure risk minimisation, engaging in risk assessment and ethics review processes is an important part of learning to be a competent and ethical researcher. Students should be expected to consider risk assessment and ethical practice as an integral element of all research. This will be an essential element of undergraduate research-based dissertations where students exercise a degree of choice in topic and research design.

Higher education institutions vary in their organisational and ethics review structures, such that one psychology department may have a formally established ethics committee

with devolved responsibilities for review while another may have a panel system for reviewing that reports to a faculty or institutional level ethics committee. A common feature of whatever process exists must be an adequate system that can assure proper and proportionate oversight and review of student research that is transparent and open to external scrutiny. Conflicts of interest must be clearly avoided. This means that the review of students' proposed research only by their immediate supervisor does not constitute

an adequate process unless the research is patently minimal risk. All student research designs should be reviewed by at least one independent reviewer. Where a standard pre-planned research design is being followed by groups of students, a single review of the design can be appropriate, but students must be made aware that this review has been carried out, and part of the learning process must include engagement with the risk assessment and an understanding of the significance of ethics review processes.

14. Student research

All student research is expected to comply with the four principles as set out in this *Code of Human Research Ethics*. The following guidance should be interpreted by departments with reference to the principles and local circumstances. It is intended primarily to support ethical undergraduate student research. For research conducted by students in schools, supporting ethical research should still be a priority, but for research by school students that is of minimal risk alternative means may need to be established to ensure review that complies with the principles.

Normally, all student research should be reviewed by at least two members of academic staff (at least one of whom should be a member of the Society or other appropriate professional organisation) on the basis of a written ethics protocol. In some circumstances generic approval will be appropriate for

research studies that are highly structured and of minimal risk and will be conducted by a number of students. In such cases, at least two reviewers should be involved

Student work sometimes falls into the same category as staff research; it may form part of a larger study and data may be intended for publication. Where the student plays a significant role in the design of their contribution and is taking responsibility for its ethical conduct, despite the likelihood that it will be closely supervised and will already have been given a favourable ethics opinion at project level, it should be the subject of the student's own independent ethics submission. Where there is any discrepancy between requirements imposed for the student's ethics protocol and the staff project protocol, these issues should be discussed with the supervisor concerned.

14.1 THE PURPOSE OF ETHICS REVIEW

Some student work will be conducted essentially or exclusively for training purposes (individually or as a class exercise). In this case, completing the ethics review procedure has a dual function: first, it is a teaching and learning experience, and second, as for any other ethics submission, it is a formal exercise that seeks to protect participants, researchers and other stakeholders from harm. In some cases, an ethics review application may be graded as an assessment, implying an acceptance that some student submissions will contain significant errors. If this practice is followed, a final version should be produced (agreed with the supervisor or other staff member) that is suitably corrected to comply with the formal requirements. Where the prime focus of a student project is training rather

than generating a novel research output, the training should include an acceptance of the limitations to contributions to knowledge of student research, while also inculcating recognition of the societal value of research.

It is important to keep in mind the distinction between an ethics opinion issued as an outcome of an ethics review process and the granting of approval to proceed. The former should be an independent evaluation while the latter carries a responsibility for ongoing governance. These two are effectively elided where student research is reviewed by departmental staff but it is good practice to make students aware of the difference.

14.2 'FAST-TRACKING' ETHICS REVIEW

In most cases, student work will be non-controversial. If so, and if a 'fast-track' route is available for ethical review, it should be used. Processes should be in place to identify where there are sufficient concerns about student work for fuller ethics review to be necessary.

Adopting a streamlined process may be needed when large numbers of student ethics submissions have to be processed and signed off rapidly. Where such a 'fast-track' route is adopted, caution should be exercised since a student might believe a piece of proposed work to be entirely innocuous and raise no significant ethics issues, but close inspection might reveal otherwise. For example, a questionnaire on perceived body image, distributed among adolescent girls, was regarded by a student as factual and neutral but actually created considerable anxiety among the participants, requiring counselling follow-up. Accordingly, it should always be a staff member/supervisor who signs off 'fast tracking', not the student, and it is good practice, even in the case of routine research (for example, creating practice questionnaire items within a methodology class) that a sufficient description of the research is provided to allow a decision by the member of staff (or of the ethics committee) involved in the fast-tracking.

Where research is conducted as a class exercise, it is good practice for the responsible teaching staff member to have obtained a single, generic favourable ethics opinion for the protocol. However, even in this situation it can be a valuable learning experience for students themselves to complete an ethics review proforma on at least one occasion for such an exercise, since it alerts them to the ethics issues that need to be considered when undertaking research, and it requires the student to read and think about the Society's ethics codes. Further, it provides valuable training in completing ethics review submission documents that will prove useful later in their careers when conducting research. Ethics review forms should require confirmation that the applicant has read and understood the Society's published codes. Note that laboratory classes can sometimes raise significant ethics issues, such as a need to screen participants to exclude those with specific medical conditions, or ensuring, for example, that participants understand that to avoid ceiling effects in an experiment, no-one will achieve 100 per cent success in the task. Without such information, a participant might come away from the experiment with a feeling that they have 'failed the test', with consequent potential negative effects on their self-esteem.

14.3 SCIENTIFIC INTEGRITY

Where a research proposal is submitted for work intended to contribute to the scientific literature, one aspect of ethics review concerns the quality of the study (see earlier Section 2.2 on Scientific integrity) and whether participation, which occupies participants' time, is warranted by its import and value. To avoid unnecessary replication, some ethics review procedures require a proposer to confirm that they have conducted an exhaustive literature search to ensure that the proposed project has not been conducted previously elsewhere and that the development of new methods is not being proposed where

properly validated methods already exist to adequately address the research question. Although ethics review is primarily aimed at avoiding harm to participants, assessing the quality of a research exercise is also important. For example, an ethics reviewer might detect a major design flaw, or believe that the exercise is so trivial as to be worthless. However, there may be occasions where allowing minor design flaws or other deviations from best scientific practice to be experienced can fulfil a valuable educational function.

In such cases students should be made aware that this is the case. Clearly, where students test each other in class, such issues are of little consequence, since much can be learned by the student trainee, and participants, from the conduct of a flawed experiment. The flaw should be pointed out to the student in the course of conventional feedback from

tutors rather than via an unfavourable ethics opinion. Where, for a more substantial piece of scientific work, an ethics reviewer detects what they believe to be a serious design flaw, this should be discussed in person with the applicant/supervisor, and referred to a third party as necessary.

Appendix: Sample ethics review application proforma

This template is provided for adaptation as appropriate to different contexts.

PROJECT IDENTIFICATION AND RATIONALE

1. Title of project

A short, clear and descriptive project title.

2. Abstract

A summary of the main points of the research, stating the research question and written in terms easily understandable by a non-specialist and containing no complex technical terms (maximum 200 words).

PROJECT PERSONNEL AND COLLABORATORS

3. Investigators

Give names and institutional attachments of all persons involved in the collection and handling of individual data and name one person as Principal Investigator (PI).

Principal Investigator/
(or Research Student): _____

Other researcher(s): _____

For students only:

Please note that this application cannot be processed without your supervisor's signature and supporting comments

Postgraduate research degree
(e.g. EdD/MRes/PhD): _____

Personal identifier _____

Supervisor _____

Supervisor's
Email address _____

Supervisor's
electronic signature: _____

Supervisor's supporting comments:

RESEARCH PROTOCOL

4. Schedule

Time frame for the research data collection phase(s):

From: _____ To: _____

Earliest date participants will be contacted: _____

5. Methodology

Outline the method(s) that will be employed to collect and analyse data. Any relevant documents, such as interview or survey questions should be sent with the completed application form.

6. Participants

Give details of the population targeted or from which you will be sampling and how this sampling will be done. Give information on the diversity of the sample.

7. Recruitment procedures

Give details of how potential participants will be identified and approached. Detail any possibility of coercion or conflict of interest and how this will be addressed. Describe steps to be taken to avoid coercion or to take potential power dynamics into account.

8. Recompense to participants

Give details of any recompense which will be offered to research participants or volunteers, e.g. a small payment or gift voucher. Participants should not be disadvantaged so it is acceptable to compensate them for their time, although it should not be considered a benefit or inducement.

9. Consent

Provide information on how valid consent will be sought from participants and attach copies of the proposed contents of the means of informing participants and seeking and recording consent. Consent and information texts **must** include the following or a rationale must be given as to why they should not:

- Contacts; the PI and an alternative contact, e.g. Head of Department or supervisor, with respective email addresses.
- Consent information must specify a date after which participants cannot withdraw their consent and details of deadlines for destruction of primary data on request. All research projects should indicate a date by which data will have been de-identified and amalgamated and therefore cannot be excluded from a dataset.
- Information on how research data will be stored and disseminated/published and destroyed or retained, including plans for open datasets.
- All information given to potential participants should include the statement: 'This project has been reviewed by, and received a favourable opinion from the XXX Ethics Committee, reference xxxx/xxxx'
- If you are offering to share a summary of results with participants, information must include a means for participants to indicate that they would like to receive the summary, and an opportunity to give their email address, so the researcher can send the summary.
- To comply with GDPR regulations, the consent process must provide participants with the opportunity to explicitly 'opt in' to each element of the research that will be released into the public domain e.g. a quote from an interview. The element of research in question should be stated explicitly, and a check-box provided, so the participant can indicate that they have consented.

10. Location(s) of data collection

Give details of where and when data will be collected, with an explanation of why the research needs to be conducted in the chosen setting or location. If it will take place on private, corporate or institutional premises, indicate what approvals are gained/required.

11. Literature review

Provide a brief review of the existing literature or previous research. Clarify whether the proposed study replicates prior work and/or duplicates work done elsewhere and/or has an element of originality (maximum 200 words).

KEY ETHICS CONSIDERATIONS

12. Published ethics and legal guidelines to be followed

Detail which guidelines will be followed by the researchers.

13. Data protection and information security

If your research involves the collection or processing of personal data it will need to be registered with an institutional Data Protection officer - please confirm that this has been done. Regarding storage and disposal of data, you need to detail below the procedures and schedule (including dates) that you will be following. Indicate the earliest and latest date for the destruction of original data, where it is required, or any archiving arrangements that have been agreed/permitted, and ensure this is included in the project schedule.

14. Research data management, disseminating and publishing research outcomes

If not covered elsewhere in your application, please give details of how your research data will be managed including retention, archiving, destruction and publishing open datasets. It is recommended that all researchers applying to XXXX REC write a Data Management Plan (DMP). Any funding body requirements should also be provided, e.g. the Economic Social Research Council (ESRC) requests data is deposited in a repository.

15. Deception

Give details of the withholding of any information from participants, or misrepresentation or other deception that is an integral part of the research. Any such deception should be fully justified.

16. Risk of harm

Detail any foreseen risks to participants or researchers, e.g. home visits, and based on a risk assessment, the steps that will be taken to minimise or counter these. If your proposed research involves children or adults lacking capacity or who are otherwise vulnerable, confirm that the requirements of the Disclosure and Barring Service have been met by providing the relevant reference number and period covered - for each member of the research team expected to have direct contact with participants. Have you considered offering participants information or contacts for emotional support if needed? If so, give details.

17. Debriefing

Give details of how information will be given to participants after data collection to inform them of the outcomes of their participation and the research more broadly.

PROJECT MANAGEMENT

18. Research organisation and funding

Please provide details of the principal funding body (internal or external).

Funding body:

Project reference number:

19. Other project-related risks

You should identify any additional risks associated with your project, which have not been identified elsewhere in the proposal. Indicate how research risks will be limited by detailing anticipated or potential problems.

20. Benefits and knowledge transfer

State how the research may be of general benefit to participants and society in general (100 words maximum).

21. Supporting documents

Include as attachments or appendices, any documents related to your research proposal. Add the XXX REC reference number to each (if already known), and list below, for example:

Consent and Participant information – for each participant group	
Questionnaire	
Email or letter from the organisation agreeing that the research can take place	
Draft bid or project outline	
Publicity leaflet	

22. Declaration

I declare that:

- The research will conform to the above protocol and that I will inform the XXX REC of any significant changes or new ethics issues and have these agreed before they are implemented.
- I have read and will adhere to the following institutional policy:
 - Ref to policy

Principal Investigator(s)

Faculty/department/school

Telephone

E-mail

(please use your institutional email address)

Signature(s)

(scanned or electronic)

Date

FINAL REPORT

At the end of a reviewed research project, Principal Investigators are required to assess their research for any ethics-related issues and/or major changes. Where these have occurred, the PI should return an explanatory report.

Final reports are confidential and only made available to the REC Chair and Committee members, and are requested to inform the review process, to assess how any ethics-related issues and major changes have been dealt with and to ensure that research has been carried out as agreed. Add the date when your research is due to finish below; you will be sent a reminder.

Proposed date for final report: _____

NB. Research students should enter their end of research project date

Research ethics applications – collection and use of data

Information provided as part of a research ethics application, e.g. from research students or staff, is stored so the XXX REC has an accurate record. All data are managed and held securely and only shared with XXX REC members as part of the research ethics review process.

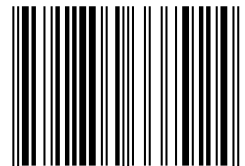


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