

Code of Research Ethics Metanoia Institute

Background

1.1 Introduction

This Code sets out a set of general principles that are applicable to all research contexts and are intended to cover all research with human participants.

Researchers should respect the rights and dignity of participants in their research and the legitimate interests of stakeholders such as funders, institutions, sponsors and society at large.

There are numerous reasons for behaving ethically. Participants in psychological research should have confidence in the investigators. Good research is only possible if there is mutual

respect and trust between investigators and participants. 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, no Code can replace the need for researchers to use their professional and ethical judgement. Fundamentally, thinking is not optional.

The principles outlined in this document supplement the general ethics principles in the Metanoia's Code of Ethics and Conduct. Both sets of principles are tools for making reasoned judgement. Members of Metanoia are expected to abide by both the Code of Ethics and Conduct and also this Code of Human Research Ethics.

1.2 Definitions of terms

Throughout this document, 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 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 fetuses, 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).

'Participant'. It is now common practice to refer to a person who serves as a data source for research as a 'participant'. This recognises their active role and replaces

the term 'subject' which has been viewed as portraying people as passive recipients rather than active agents. While the extent of active 'participation' in the research over and above providing information will of course 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 at any time without penalty. We recognise that the term 'subject' has currency in certain contexts, such as describing research designs (e.g. 'within subject').

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 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, as noted above

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, anonymised at source 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 adequate liability cover. Human research also involves a wide variety of target 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 aim of covering all eventualities, is seen by many ethicists as an ultimately flawed direction of travel. 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 flawed. Overly detailed regulations may also make it more difficult for 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. This Code introduces the notion of underlying principles to inform psychological research practice. By openly stating the values that underpin psychological research, 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 and Dignity of Persons.
- Scientific Value.
- Social Responsibility.
- Maximising Benefit and Minimising Harm.

2. The Principles

2.1 Respect for the autonomy and dignity of persons

Value statement: ‘Researchers value the dignity and worth of all persons equally, with sensitivity to the dynamics of perceived authority or influence over others and with particular regard to people’s rights including those of privacy and self-determination’ (BPS Code of Ethics and Conduct, 2009, p.10).

Adherence to the concept of moral rights is an essential component of respect for the dignity of persons. Rights to privacy, self-determination, personal liberty and natural justice are of particular importance to psychological researchers, and they have a responsibility to protect and promote these rights in their research activities. As such, psychological researchers 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: Psychological researchers have respect for the autonomy and dignity of persons. In the research context this means that there is a clear duty to participants. For example, psychological researchers respect the knowledge, insight, experience and expertise of participants and potential participants. They respect individual, cultural and role differences, including those involving age, sex, disability, education, ethnicity, gender, language, national origin, religion, sexual orientation, marital or family situation and socio-economic status.

Given this level of respect psychological researchers are naturally willing 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 request that their data be destroyed. Under such circumstances researchers will comply with any requests that any related data be destroyed, and removed from any datasets.

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.

Psychological researchers 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 ensure that individuals are not personally identifiable, except in exceptional circumstances and then only with clear, unambiguous informed consent. They will respect confidentiality, and will ensure that information or data collected about individuals are appropriately anonymised and cannot be traced back to them by other parties, even if the participants themselves are

not troubled by a potential loss of confidentiality. Where a participant wishes to have their voice heard and their identity linked with this, researchers will endeavour to respect such a wish.

In their research, as in all other professional dealings, psychological researchers will seek to ensure that people's rights are respected and protected.

2.2 Scientific value

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 promulgated and can have the potential to cause harm.

Ethics standards: Researchers are committed to ensuring that the scientific and scholarly standards of their research are accountable and 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). In the event that the scientific or scholarly merit of a research proposal is questioned, ethics approval should be withheld until such concerns are positively addressed by the researcher concerned. Principles for ethics review can be found in Section 9 of this Code. See also section 10.4 on student research.

2.3 Social responsibility

Value statement: A shared collective duty for the welfare of human and non-human beings, both within the societies in which psychological researchers live and work, and beyond them, must be acknowledged by those conducting the research.

In whatever social context they work, researchers should acknowledge the evolution of social structures in relation to societal need and be respectful of such structures. Unwarranted or unnecessary disruption should be avoided unless the researcher judges that the benefits of intervention outweigh the costs of such disruption (for example, in the protection of vulnerable individuals or groups).

Ethics standards: Psychological knowledge must be generated and used for beneficial purposes. Such purposes 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 contribute to the 'common good'.

Accordingly, researchers 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.

Psychological 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.

2.4 Maximising benefit and minimising harm

Value statement: Psychological researchers should consider all research from the standpoint of the research participants, with the aim of avoiding potential risks to psychological well-being, mental health, personal values, or dignity.

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

Harm to research participants must be avoided. 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 must be no greater than that encountered in ordinary life, i.e. participants 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. If unavoidable additional risks are present, researchers should assess these risks for their probability and severity, and put in place measures to obviate, minimise and manage such risks.

Researchers need to be sensitive to the potential impact of their interventions, for example to the possibility of individual distress that may be caused unwittingly, to the danger of 'normalising' unhelpful behaviours or to creating self-doubt. A difference in power inevitably exists between researchers and participants, even if researchers seek to minimise it. Sensitivity is therefore essential, and caution is usually necessary. In conjunction with the previous section of this Code 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.

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 personal social status, privacy, personal values and beliefs, 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 is important to acknowledge that 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 applied.

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

- Research involving vulnerable groups (such as children aged 16 and under; those lacking capacity; or individuals in a dependent or unequal relationship);

- Research involving 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 element of deception;
- Research involving access to records of personal or confidential information (including genetic or other biological information);
- Research involving access to potentially sensitive data through third parties (such as employee data);
- 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 hypnotherapy) 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 Research Ethics Committee.

Risk analysis should not only be confined to considering the interests of the primary participants, 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

Psychological researchers should ensure that every person from whom Data are gathered for the purposes of research consents freely to the process on the basis of adequate information. They should be able, during the data gathering phase, freely to withdraw or modify their consent and to ask for the destruction of all or part of the data that they have contributed.

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 anonymised-at-source, non-sensitive data, consent may be considered to have been given by the act of participation or by ticking a box, for example. Nevertheless, the risks involved in some anonymised-at-source research, for example, web-based research on sensitive topics such as sexual behaviours, will require carefully prepared prior information and clear consent processes.

When research involves the collection of identity capturing data on sensitive topics, using video or audio recording, or other methodologies where an individual may be identifiable, 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.

Assessment of 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 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.

Who can give consent? (see also Section 10.1)

The consent of participants in research, whatever their age or competence, should always be sought, by means appropriate to their age and competence level. For children under 16 years of age and for other persons where capacity to consent may be impaired the additional consent of parents or those with legal responsibility for the individual should normally also be sought. In special circumstances such as where it may be important that views of such participants or findings about them should not be suppressed, the rationale for not seeking parental consent should be clearly stated and approved by a REC.

In the case of very young children, and persons with very limited competence, their assent should be regularly monitored by sensitive attention to any signs, verbal or non-verbal, that they are not wholly willing to continue with the data collection.

If valid consent cannot be obtained from adults with severe impairments in understanding or communication, the investigator should consult a person well-placed to appreciate the participant's reaction, such as a member of the person's family, and must obtain the disinterested approval of the research from independent advisors. Where the research falls within the regulatory framework of the Mental Capacity Act, the Adults with Incapacity (Scotland) Act or relevant legislation in Northern Ireland, approval must be sought from a recognised REC.

Where competence to consent is in question, it should be assessed using a systematic procedure such as engaging the potential participant in a dialogue to explore their understanding of what it is that they are consenting to. This process may usefully include offering a choice to which the response indicates whether the individual is capable of making decisions based on likely outcome.

In relation to the gaining of consent from children and young people 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. 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 parental consent from children under 16 years of age and young people of limited competence.

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.

Informing participants

Giving potential participants sufficient information about the research in an understandable form requires careful drafting of the information sheet. It is recommended that at least one pilot test of the processes for informing and debriefing participants be carried out with a naïve person having a literacy 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 information sheet 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 sheet 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 and Freedom of Information Act.
- 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 time and inconvenience associated with participation will be given, without specifying the amount or nature of such recompense 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 used and planned outcomes.
- 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 should be clear and accessible to people with limited literacy, using short words and sentences, written in the active voice, and avoiding the use of technical terms.

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.

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. 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.

It is crucial that participation in a research study is not coerced in any way, for example, through offering disproportionate rewards for consenting or indicating disincentives for not consenting. Coercion infringes the human right to autonomy and coerced participation compromises the validity of research 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 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. However, it is acceptable, and in many cases proper, for reasonable recompense for attendance, travel, other incurred costs and the time and inconvenience of participation to be offered.

Need for 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, 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. 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.

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, the appropriate source of professional advice should be recommended.

7. Deception

To many outside the psychological therapies, and to some within it, the idea of deceiving the participants in research is seen as quite inappropriate. 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 researchers. However, since there are very many psychological processes that are modifiable by individuals if they are aware that they are being studied, the statement of the research focus in advance of the collection of data would make much 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 expects all researchers to seek to supply as full information as possible to those taking part in their research, recognising that if 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 obviate any potential harm arising from such withholding. Deception or covert collection of data should only take place where it is essential to achieve the research

results required, where the research objective has strong scientific merit and where there is an appropriate risk management and harm alleviation strategy.

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.

8. Debriefing

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.

9. Further Guidance

This section gives consideration to aspects of human research ethics where additional risks are likely to be present.

9.1 Safeguards for working with vulnerable populations

Special safeguards need to be in place for research with vulnerable populations. Vulnerable populations include children under the age of 16, people with learning or communication difficulties, patients in care, people in custody or on probation, and people engaged in illegal activities, such as drug abuse.

In accordance with the Principle of Respect for the Autonomy and Dignity of Persons, researchers should ensure that participants from vulnerable populations (such as children, persons lacking capacity, and those in a dependent or unequal relationship) 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 understanding and ability to consent of such vulnerable persons to give informed consent 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.

9.1.1 Children

If the vulnerable person is unable to give informed consent, consent should be sought from those persons who are legally responsible or appointed to give consent on behalf of persons not competent to consent on their own behalf, seeking to ensure that respect is paid to any previously expressed preferences of such persons. In research with children under the age of 16, and in specific circumstances as described above in Section 4 on Valid Consent, researchers should ensure that parents or guardians are

informed about the nature of the study and given the option to withdraw their child from the study if they so wish. The principle of monitoring the assent of the child will also apply.

9.1.2 Persons lacking capacity

In the specific case of persons lacking capacity to give valid consent, willing and fully informed consent for participation should be sought from a legally responsible proxy; and research without consent from a person should normally only occur if the research activity is considered to provide direct benefit to that person. Specific regulation applies to clinical trials. Further consideration and guidance on this matter can be found in the BPS guidelines on

Conducting Research with People Not Having the Capacity to Consent to Their Participation

9.1.3 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) and should ensure that appropriate consents are obtained from any gatekeepers to participants, for example school principals, parents or legal guardians.

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

This Code 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.

9.2 Research within the National Health Service (NHS)

This guidance has been developed to summarise the ethics review process that applies to psychological research that requires NHS approval, which is organised through the National Research Ethics Service (NRES).

Ethics review for research involving the NHS is normally sought from a local Research Ethics Committee (REC) except for research at multiple NHS sites, in which case the application is made through the central NRES system.

Detailed information about applying for ethics review for research in the NHS can be found on the NRES website.

9.2.1 How to decide if your research requires NHS approval

Not all projects undertaken within the NHS are classed as research. In particular, if your study is an audit or service evaluation then it will not normally be classed as research and, therefore, will not require NRES review. This does not mean that no ethics review is required; for example, research involving human participants that is conducted by staff in a university will normally require review by the university REC even if NRES review is not required.

Guidance on determining where a research project falls within the NHS definitions can be found on the NRES website.

9.2.2 The remit of the NHS REC

NRES advises that:

Ethical advice from the appropriate NHS REC is required for any research proposal involving:

- Patients and users of the NHS. This includes all potential research participants recruited by virtue of the patient or user's past or present treatment by, or use of, the NHS. It includes NHS patients treated under contracts with private sector institutions.
- Individuals identified as potential research participants because of their status as relatives or carers of patients and users of the NHS, as identified above.
- Access to data, organs or other bodily material of past and present NHS patients.
- Foetal material and IVF involving NHS patients.
- The recently dead in NHS premises.
- The use of, or potential access to, NHS premises or facilities.
- NHS staff, recruited as research participants by virtue of their professional role.

(Source: NRES web site, Requirements of Research in the NHS)

Furthermore if your study involves the following it will require ethical approval from an NHS REC:

- A prison or a young offender institution.
- A private hospital/care facility and any of the patients who are there because they have been either referred by the NHS or the facility is under contract with the NHS. (Source as above.)

If your research falls into any of the categories as described above then you will need to apply to an NHS REC for approval

9.2.3 Applying for ethics review

Once you have established that NHS REC approval is required then you will need to engage with the NRES process.

It should be noted that the first point of call for researchers should be the Research and Development Office(s) of the NHS area(s) where it is planned to carry out the research (these can be approached via the Integrated Research Application System).

9.2.4 The online application process (IRAS)

Previously the process for applying for REC NHS approval required paper-based forms to be completed. However, since the introduction of the new Integrated Research Application System (IRAS) this method should be used to place all NHS REC applications. To access this system you should visit the NRES website.

Instructions and advice on how to complete the form are contained on the website.

It is important to ensure you have conditional funding before you make an NHS REC application as this will assist in ensuring that the application reaches REC review.

10. Student Research

Student research is expected to comply with the four principles as set out in this Code. All student research should be reviewed by at least two members of academic staff on the basis of the Metanoia research ethics protocol. In some circumstances generic approval for a research study that will be conducted by a number of students will be appropriate.

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. If so, despite the likelihood that it will be closely supervised and will already have been granted ethics approval 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 approval and staff project approval, these issues should be discussed with the supervisor concerned.)

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.

Scientific value

Where a research proposal is submitted for work intended to contribute to the scientific literature, one aspect of ethics approval concerns the quality of the study (see earlier Section 2.2 on Scientific Value) 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 assessor might detect a major design flaw, or believe that the exercise is so trivial as to be worthless. 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 ethics refusal. 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, but this does not preclude the granting of ethics approval.

11. Acknowledgements

This Code was derived from the British Psychological Society Code of Human Research Ethics.

**Metanoia Institute Code of Research Ethics 2015
For review July 2016**