

# FamilyMatters

exploring better ways of getting on together

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## Research Policy

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## 1. Introduction

Researchers must 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.

**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.

## 2. Respect for the autonomy and dignity of persons

**Ethics standards:** Researchers must 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, they must 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 researchers must naturally be 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. Researchers will 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. Researchers will seek to ensure that people's rights are respected and protected.

### **3. Scientific value**

Researchers will be 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.

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 3.0) 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 to a student. In such cases the flaw should be pointed out to the student in the course of conventional feedback 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.

### **4. Social responsibility**

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. 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.

### **5. Maximising benefit and minimising harm**

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 policy. 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 policy 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.

## **6. 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. 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. 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.

## **7. Valid Consent**

In accordance with this policy, 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. 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.

### **7.1 Who can give consent?**

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 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.

### **7.2 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.

### **7.3 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.

#### **7.4 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 on-going 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.

## **8. 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.

## **9. 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.

## **10. Deception**

To many, outside research 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 therapists. 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 policy 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.



## 11. 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.

## 12. Principles of Best Practice in Ethics Review

This section of the policy sets out principles for ethics review outside of the National Research Ethics Service (NRES) 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.

The principles are:

- **Independence**

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

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 conditioned by the fourth principle, which requires recognition of the responsibility of RECs and the need to formulate this clearly. It also invokes the need for external membership of RECs (eschewing the problematic term 'lay'). It is important to recognise the distinction between the review of research ethics and the subsequent governance of approved research.

- **Competence**

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

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. In addition to the core duty of responding to applications for ethics review with constructive 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.

RECs need to recognise their responsibilities and to be appropriately located within organisational structures that give transparency to the REC operation and procedures to maintain and review standards.

### 12.1 The role of a Research Ethics Committee (REC)

An REC is normally responsible for:

- reviewing all 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
- making informed recommendations to the researcher if the proposal is found to be wanting in some respect.

## **12.2 The constitution of a Research Ethics Committee**

An REC should normally:

- be multidisciplinary;
- include both men and women;
- include at least one appropriately trained external member with no affiliation with the organisation, 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 who is knowledgeable in ethics;
- include individuals who reflect the ethnic diversity of the local community; users of specialist health, education or social services where these are the focus of research activities; individuals with experience of professional care or therapy; and individuals with specific methodological expertise relevant to the research they review;
- be constituted so that conflicts of interest are avoided.

This would normally mean that a REC comprises at least 5 members.

## **12.3 Monitoring**

All research organisations should establish appropriate 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.

Where an 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. Further Guidance

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

### **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 and the *AFT Code of Ethics* 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.

#### **13.1 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.

#### **13.2 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.

#### **13.3 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. 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. This policy 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.

## **14. Independent practitioners**

An increasing number of independent practitioners and researchers seek ethics review for their proposed research. If the research is being conducted within the NHS, the individual should contact the NRES for further guidance. If the research is not being conducted within the NHS, the individual should explore the possibility of obtaining ethics guidance and review from a local university. Universities usually have well established procedures for ethics review, and it may be the case that approval or sound advice could be obtained via this route. If the research involves social care, it may be possible to obtain ethics review through the national Social Care Research Ethics Committee. Should review through NRES or a University Research Ethics Committee not be possible, it is advised that the following overarching principles are followed. The individual should be able to demonstrate that:

- their research proposal was reviewed by an independent person or persons competent to judge ethics standards;
- they believed they had acted within the ethics standards laid down in relevant guidance documentation (such as the *AFT Code of Ethics* and this policy); and
- evidence to this effect could be provided if necessary.