UNIVERSITY OF CAMBRIDGE
School of Biological Sciences

CAMBRIDGE HUMAN PSYCHOLOGY RESEARCH ETHICS COMMITTEE

HANDBOOK

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17 Mill Lane
Cambridge CB2 1RX

Telephone: 01223 766876
Fax: 01223 332355
E-mail: cheryl.torbett@admin.cam.ac.uk

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1.1 Introduction

1.1.1 Background

The University of Cambridge has a long-standing commitment to the highest standards of ethics in research. Over time, discipline-specific policies and processes have developed to ensure that research at Cambridge not only meets the requirements of legislation and research sponsors, but also satisfies the standards of disciplinary best practice adopted by peers. The University is committed to providing a rigorous and independent ethical review process for research involving human participation or personal data. There are four School-level research ethics committees at Cambridge that can provide appropriate guidance and review for most research projects within their disciplinary remits. These are:

- The Cambridge Human Biology Research Ethics Committee - http://www.bio.cam.ac.uk/sbs/hbrec/
- The Cambridge Psychology Research Ethics Committee - http://www.bio.cam.ac.uk/sbs/psyres/
- The Humanities and Social Sciences Research Ethics Committee - http://www.cshss.cam.ac.uk/committees/ethics/
- The School of Technology Ethics Committee - http://www.tech.cam.ac.uk/school/Research

1.1.2 Remit

The Cambridge Psychology Research Ethics Committee considers applications for ethical approval for research programmes in human psychology. The Committee may consider applications involving neuro-imaging, administration of pharmaceuticals to healthy volunteers and use of NHS facilities where no patients are involved.

Applications for ethical approval for investigations in human biology, other than psychology, should be made to the Cambridge Human Biology Research Ethics Committee.

The Committee does not consider applications for research requiring ethical approval from the National Research Ethics Service (NRES). NRES approval is required for several types of research including:

- Studies involving patients attending NHS clinics or users of any of the services for which UK Health Departments are responsible. This includes adult social care in England and both adult and children's social care in Wales and Northern Ireland.
- Studies involving research participants identified because of their status as relatives or carers of past or present users of the services listed above.
- Studies involving collection of tissue or information from any users of these services, including those who have died within the last 100 years, or the use of previously collected tissue or information from which the research team could identify individual past or present users of these services, either directly from that tissue or information, or from its combination with other tissue or information in or likely to come into their possession.
- Health-related research projects involving prisoners.
- Studies involving intrusive procedures with adults who lack capacity to consent for themselves, including participants retained in the study following loss of capacity. Intrusive procedures are those requiring consent in law, including use of identifiable tissue samples or personal information.

- Studies involving exposure to ionising radiation.

For further information on the need for NRES approval, please refer to http://www.hra-decisiontools.org.uk/ethics/index.html

1.2 Terms of Reference

1.2.1 Scope

The Committee considers the ethics of research projects with human participants referred to it by members of the staff of University departments, colleges and MRC Units, and their collaborators. It is for departments and units to determine what projects should be referred to the Committee, although advice may be sought from the Committee if required.

The Committee holds records of ethical approvals granted by external higher education institutions or organisations of similar standing, to research projects with human participants undertaken within departments and units of the University of Cambridge. The policy and guidelines of the Committee comply with those of the University Research Ethics Committee (UREC), to which an Annual Report is submitted.

1.2.2 Membership

All members of the Committee are appointed by the Council of the School of the Biological Sciences. The membership includes nominations from University departments and Medical Research Council Units covering a range of research areas in psychology, as well as a lay person. Additional persons may be co-opted for their specialist knowledge. The Committee has at least one medically qualified member and access to legal advice when necessary.

There are currently 14 members on the Committee, although this is not fixed. Membership is normally for three years and is renewable.

1.2.3 Procedure

The Committee maintains a web site http://www.bio.cam.ac.uk/psyres where application forms may be downloaded, along with advice on the preparation of applications and links to other relevant information. The review procedure is entirely electronic; that is, via email. The Committee does not meet in person on a regular basis.

In accordance with University policy, research involving human participants or personal data should not begin until proper ethical review has taken place and approval given. Retrospective ethical reviews are therefore not permitted**.**

Applications must include a completed and signed application form, along with relevant supporting documentation. Further help and advice is available on the web-site, Handbook and in the notes that accompany the application form. The Committee require that applications for research projects which will be carried out by research students or junior research assistants have a more senior Primary Applicant, such as their supervisor.

Signed Application forms plus supporting documentation are submitted to the School office (either electronically or via hard copy). The applicant will be informed, via email, that the application has been received and circulated to the Committee for review.

Once received and acknowledged, applications are allocated a reference number (PRE.YYYY.NN) and then circulated to Committee members for review, normally within 5 days of receipt. Applications are circulated to at least two Committee members for review. Reviewers are chosen from the Committee on a rotating basis, excluding members from the same department or unit as the Primary Applicant. Applications from Committee members will not be reviewed by that member.

Committee members' email comments/concerns by an agreed deadline to the Administrator who will then consolidate them. A composite review highlighting any concerns raised is then returned to the applicant to address.

Applicants should address the comments in a covering letter and indicate any amendments to the Application Form and supporting documents using text highlighting or similar. These will be passed back to the Committee for approval.

The Administrator will contact the applicant notifying him/her that approval has been granted and a formal letter (signed by the Secretary of the Ethics Committee) will be sent to all named applicants.

Ethical approval of the project will relate to the application as submitted and as described in the documents before the Committee. If an amendment (see below) is later made to the project, the applicants should write to the Committee indicating what changes have been made and why they are needed, providing copies of any documentation that has been updated.

It should be noted that the timeframe is dependent upon volume of work; for example, in the run up to the summer or Christmas vacation when the number of applications increases significantly, processing can take up to 12 weeks; however, in general, the aim is to complete the entire process within a 6-8 week timeframe**.**

1.3 Amendments following ethical approval

Amendments are changes to the procedures involved in undertaking a study. An amendment does not change the study objective or the introduction of new research questions. Furthermore, the integrity of the study should be preserved; that is, sub-studies cannot be cleaved from the original study. Any such change requires a new application.

Examples of valid amendments are:

- Changes to Participant Information Sheets explaining procedures
- Changes to the size of the sample
- Recruitment of participants with new procedures
- Additions or replacements of assessments that better address the study objectives
- Changes to personnel (other than the Principal Applicant)

Examples where new applications are needed are:

- Replacing the intervention under investigation
- Changing the study population (for example, from adults to children)
- Undertaking a subset of the assessments to answer a separate research question
- Introducing an assessment that opens a new research question
- Changes to the Principal Applicant

To inform the Committee of an amendment, investigators should write to the Committee explaining what the amendment entails and why it is needed. New versions of any documentation that has been changed should be included. If the amendment alters any of the study procedures, the original application form should be updated making clear what the changes are.

1.3.1 Appeals

Appeals on decisions made by the Committee are referred to the Council of the School of the Biological Sciences; in the unlikely event of further appeal, cases will be referred to the UREC. Details are available on the relevant webpages.

1.3.2 When is ethical approval not required?

If a study does not collect any identifying information from participants (including photos and videos), the participants are not from any vulnerable group (including individuals under 16 years old), and the interactions with, and observations made by investigators are not intrusive or use deception and do not pose any risk, then ethical approval is not necessarily required. Nevertheless, investigators should ensure that all participants are fully informed of the study.

2 Guidance

2.1 Documents consulted

In developing this Handbook, the Committee has taken into account the following guidance:

The British Psychological Society's Code of Human Research Ethics (2010) http://www.bps.org.uk/sites/default/files/documents/code_of_human_research_ethics.pdf

The British Psychological Society's Ethics Guidelines for Internet-mediated Research (2013) http://www.bps.org.uk/system/files/Public%20files/inf206-guidelines-for-internet-mediated-research.pdf

The General Medical Council's Good Practice in Research (2013)

http://www.gmc-uk.org/static/documents/content/Good_practice_in_research_and_consent.pdf

The Medical Research Council's Ethics Guide: Medical research involving children (2004)

www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002430

The University of Cambridge policy on the ethics of research involving human participants and personal data

http://www.admin.cam.ac.uk/offices/research/documents/local/policies/Ethics_in_Research/Research_Involving_Human_Participants_and_Personal_Data.pdf

The University of Cambridge policy on good research practice

http://www.admin.cam.ac.uk/offices/research/documents/research/Good_Research_Practice.pdf

2.2 Basic Principles

The Committee aims to facilitate the conduct of worthwhile research, whilst ensuring that the interests of human participants and their personal data are given consideration and protection. Accordingly, the following are required of all applications:

- In order to give the reviewers an adequate understanding of the proposed research, the application form must be completed in full, with all questions answered and all the documentation required by the Committee (see website for details) included in the submission.

- Researchers should seek to maximise the benefits of their work at all stages, from inception through to dissemination (BPS Code 2010). Research should be designed, reviewed and conducted in a way that ensures its quality, integrity and contribution to the development of knowledge and understanding (BPS Code 2010). The application should include the outcome of any peer review already undertaken (for example, as part of a funding application) and clear descriptions of the purpose, rationale of the study, and the methods and procedures to be used. The Committee will not, themselves, attempt to adjudicate on the quality of research, but will regard it as unethical to conduct research which is clearly methodologically incapable of answering the questions or hypotheses proposed.

- Researchers have a responsibility to develop and follow procedures for valid consent, confidentiality, anonymity, fair treatment and due process that are consistent with participants' rights (BPS Code 2010). Advertising materials used in recruitment and participant information sheets should use plain, non-technical language appropriate to the needs of the potential participants. Potential participants should be given adequate time to

consider the information and come to a decision about participation. Where used, consent forms should be clear and comprehensive. Researchers should comply with the principles of the Data Protection Act: http://www.ico.org.uk/for_organisations/data_protection/the_guide/the_principles. Electronic personal data should be stored on encrypted drives.

- 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 (BPS Code 2010).

- 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 (BPS Code 2010). Appropriate insurance must be in place for all students involving human participants to meet the potential legal liability for any non-negligent harm arising out of participation in the research. University employees should contact the Insurance Section (http://www.admin.cam.ac.uk/offices/insurance/) for advice and to arrange the issue of a certificate. This certificate will need to be submitted to the REC before a letter of approval can be issued.

- 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 (BPS Code 2010). Principle Investigators remain responsible for addressing any complaints from participants, and their contact details, or that of a delegate, must be included in recruitment material/participant information sheets.

2.3 Recruitment

2.3.1 Permission from head-teachers and other organisation representatives

When recruitment or research will be carried out in or through schools, youth groups, member organisations etc., evidence that the head of the organisation, or a suitable representative, has been made aware of the proposal to recruit participants or conduct research, and agrees to this happening, should be included with the application for ethical approval.

2.3.2 Permission from Senior Tutors of colleges

In relation to the circulation of questionnaires to students, the Committee agree that gaining the approval of Senior Tutors is a courtesy that they wish to see observed, but that at the very least they would wish Senior Tutors to be informed of an intention to conduct such an investigation in a college. In relation to the circumstances in which the Senior Tutor of a college should either be informed about an investigation involving student members of the college or should have the opportunity to decide if the investigation should go ahead, the Committee agree that each application for ethical approval will be considered individually. The Committee may require as a condition of ethical approval that the Senior Tutor should give approval for an investigation, if, in the opinion of the Committee, there is a strong enough possibility that serious trauma might be caused to some student participants.

2.3.3 Recruitment of relatives or acquaintances of participants

When participants are already recruited to a study, they have the right to refuse access to any other people (acquaintances or relatives) who the investigators propose to recruit through them for this or other studies. Participants should not be put under any undue pressure either to grant access to, or to recruit any further participants for a study. Any other person recruited to the study through an original participant should be given enough time to consider if they wish to participate in the study, and they should be afforded all the normal rights of participants, including the right to refuse involvement with the study.

2.3.4 Recruitment to further studies

Following GMC guidance: You should make sure that participants are not encouraged to volunteer more frequently than is advisable or against their best interests. You should make sure that nobody takes part repeatedly in research projects if it might lead to a risk of significant harm to them.

2.3.5 Use of teachers to recruit children

It is inappropriate to ask teachers to identify children to participate in research because this may alter the teacher's perception of the child (and also because of the additional work for the teacher). Children should be enlisted by circular letters or emails to parents.

2.3.6 Voluntary participation: explicit statement in recruitment document

The Committee accept that, for methodological reasons, it may be desirable to try to obtain a high response and completion rate, but that nevertheless it is necessary to balance an attempt to get a high return rate by ensuring that potential participants are not coerced into participation. An explicit statement should normally be included in documents given to participants or potential participants to the effect that participation in the research is voluntary.

You should make sure that any necessary safeguards are in place to protect anybody who may be vulnerable to pressure to take part in research. (GMC Guidance)

2.4 Consent: Adults

2.4.1 Requirement to seek valid consent

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 (BPS guidance).

Seeking consent is fundamental in research involving people. Participants' consent is legally valid and professionally acceptable only if they have the capacity to decide whether to take part in the research, have been properly informed, and have agreed to participate without pressure or coercion (GMC guidance).

2.4.2 Form of consent

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 (BPS guidance).

The Committee do not seek to influence whether verbal or written consent is given, or to impose that consent should be obtained in a particular way. However, the Committee agree that applicants who do not wish to obtain written consent should justify this on their application form, and agree that in some circumstances verbal or passive consent will be acceptable.

In some circumstances, such as research conducted over a long period of time, or research involving audio or video recording concerning sensitive topics, it may be appropriate to seek ongoing consent at different stages of the project (for example, before each stage of a long project, or before and after recording).

2.4.3 Research involving adults who lack the capacity to consent to participation

In law, all adults are presumed to have the capacity to make decisions for themselves, unless shown otherwise. The Mental Capacity Act 2005 states that an adult lacks the capacity to make a decision for him or herself if, as a result of a 'disorder or dysfunction of mind or brain', he or she is unable to understand, retain or use and weigh up relevant information needed to come to a decision, or to communicate that decision.

Studies involving procedures for which consent is required by law (these include any procedures involving physical contact with the participant, and any studies involving the collection of information that could be used to identify the participant) must apply for ethical approval through NRES and are outside the remit of this Committee.

2.4.4 Dependent participants

Particular care needs to be taken when participants are in dependent situations to the researcher, for example students, where there is an issue of a duty of care.

2.4.5 Inducements

Information about remuneration or other 'inducements' offered to participants should be given in applications for ethical approval. Significant inducements may, in certain circumstances, prevent participants from giving truly voluntary consent.

2.4.6 Duty to ensure participants are appropriately informed

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. (BPS guidance)

BPS guidance also states: 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.

Any document given to a participant (or parent of a participant) explaining an investigation must not be difficult to understand; without a proper understanding there cannot be real consent. The level of complexity that is acceptable will depend on potential participants.

The document should, as a minimum explain adequately the purpose of the investigation, what will take place in the investigation (what will happen, how long it will take), any potential risks, what will happen to the results, and an explicit statement should normally be included in documents given to participants or potential participants that participation in the investigation is voluntary. A balance needs to be struck in order to provide sufficient information whilst avoiding overloading potential participants.

If written information is to be given to participants, and consent will be derived, at least in part, from such written information, the Committee require that such information should be available to them when an application for ethical approval is submitted. It is advisable to pilot written information by checking that a lay person can understand it adequately before submitting the application for ethical approval.

Potential participants should be given adequate time to absorb the information they have been given, and adequate opportunity to ask any questions that may arise, before consent to participation is sought.

2.4.7 Withholding information

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 It may occasionally be necessary, for methodological reasons, to withhold some information from participants. Information should be withheld only if to disclose it would nullify the investigation, and the reasons for withholding information should be justified in an application for ethical approval. (BPS guidance)

The Committee accept that a certain level of deception about the purpose of procedures may be necessary in some research projects. The Committee agree that the tests for the acceptability of deception should be: (a) that when the manipulation/deception becomes known it is unlikely to cause significant distress; and (b) that the deception is necessary for the purposes and conduct of the research. In cases where some deception is necessary for a research project, investigators should be careful about the way and manner in which consent is obtained from participants. It would not be acceptable to invite participants to sign a consent form accompanied by words such as 'it is just a consent form to show you understand fully what it is all about', in circumstances where there was deception about the purpose of the procedures. It would, however, be acceptable if participants were invited to sign a consent form to show that they understood what procedures would be used. The Committee agree that it is preferable for investigators to avoid making statements that are untrue, and that active deception (i.e. the telling of a lie) will in any case negate true consent.

2.4.8 Right to withdraw consent

Participants 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. (BPS guidance)

A participant has a right to withdraw at any stage up to aggregation/publication of data, after which it becomes impossible. Participants can withdraw during testing/data gathering, or retrospectively as a result of debriefing or for any other reason, and in such circumstances any records, film, video- or audio-recordings or notes etc., must be destroyed.

This right should be communicated to participants during the gathering of consent. Where participant information sheets and consent forms are used, information about the right to withdraw should be included.

In research projects which extend over several years, particularly those involving children, the Committee is concerned that because withdrawal of participants might damage the design of the research project, undue pressure might be exerted to persuade the participant or parent to continue participation. In such cases, the Committee will expect to receive satisfactory assurances from the investigators that withdrawal can occur at any stage and that undue pressure to continue will not be exerted.

2.5 Consent: Children and young people

2.5.1 Requirement to obtain consent

Research with children must normally only be carried out with the consent of the parent/guardian and/or child depending on the competence of the child.

Consent should be sought before a child is examined, treated, cared for or involved in research.

The [principle investigator] needs to ensure that processes are in place and adhered to that ensure that the child and/or parent/guardian have given their informed consent. However the task of seeking consent can be delegated to another suitably trained and qualified [researcher] who understands the procedure(s) for which consent is being sought. (MRC guidance)

The law regarding the child's right to consent has developed differently in Scotland than in England, Wales and Northern Ireland. Generally, where children have sufficient understanding and intelligence to understand what is proposed, it is their consent and not that of their parent/guardian that is required by law. (MRC guidance)

Generally, the consent of parents will be required although in some circumstances, outlined in the sections below, this will not be necessary. The consent of children who are competent to give consent, and the assent of those who are not, will always be required.

2.5.2 Seeking consent for research involving young people aged 16-17

Whilst not considered to have fully reached adulthood, young people between the age of 16 and 18 are presumed to be competent to give consent (MRC guidance). Furthermore, the Family Law Reform Act 1969 states that the consent of a minor who has attained the age of 16 years to medical treatment is as effective as it would be if he were of full age and it is, therefore, not essential to obtain the consent of his or her parent or guardian for a therapeutic procedure. The Royal College of Physicians, as set out in their Report on research on healthy volunteers (RCP Research/Volunteers, page 6, 'Children'), by extension considered that 16 or 17 year old children can give informed consent to participation in medical research.

The Committee conclude that participants aged 16 or 17 can give informed consent to participation in research. The Committee have previously taken the view for certain investigations that informing the parents or obtaining parental consent is unnecessary, but this depends on the circumstances. The Committee agree that in the kind of clinical research that an NRES Committee might be concerned with, parental knowledge might usually be appropriate, whereas, for example, in a study of learning attitudes in 16 and 17 year-olds, parental consent might be unnecessary.

2.5.3 Seeking consent for research involving children under the age of 16

No statute governs the rights of those under the age of 16 years to give consent for medical treatment or research. However, case law provides the example of the Gillick case with respect to treatment. This case determined that where a young person has sufficient understanding and intelligence to understand fully what is proposed, and use and weigh this information in reaching a decision, he or she can give consent to treatment and consent from parents is not legally necessary – although parental involvement should always be encouraged. The term "Gillick competent" is used to describe a young person's ability to make a decision regarding consent. In the absence of case law dealing specifically with research, the Gillick principles might reasonably be applied here, although the threshold for understanding will vary according to the complexity of the research (MRC guidance). Researchers must, therefore, seek the consent of parents before involving children under 16 years who are not competent to give consent themselves in research.

Legally, the researcher need only obtain consent from one person with parental responsibility. However, it is good practice and in the best interests of the child to involve others close to the child – for example, a second parent – in the decision-making process. Where opinions are strongly divided and agreement cannot be reached, it would be advisable to exclude the child from the research study. (MRC guidance)

The Committee considers that it is generally acceptable to seek the consent of one parent. However, in studies concerning the effects of parental separation or divorce the Committee has required the inclusion of additional safeguards:

Every effort should be made to obtain active consent from both the caretaking and the absent parent; care should be taken to avoid the assumption, in any letter or document, that it is the father who is the absent parent. In the case of the absent parent, researchers should obtain the

address of the absent parent, should write to the absent parent directly, and should attempt direct contact to obtain consent if there is no response to letters. The Committee agreed that if all efforts are made to trace the absent parent, and no contact is made then, given consent from the caretaking parent and the child, the child could be involved in the study. If one parent refuses consent, then the child must not be involved in the study. Where an order is in force preventing contact between the absent parent and the child, it would be inappropriate to contact this parent, and consent from the absent parent will not be required.

If the parents are themselves under 16 years of age, they will only be able to give valid consent on behalf of their child if they are competent to take the decision in question. (MRC guidance)

The Court in the Gillick case noted that it would be 'most unusual' for a doctor to treat a child under 16 years without the approval of his or her parent or guardian. In view of this, the Committee considers that even if an investigator believes that a child is capable of giving legally valid consent, the approval of a parent or guardian should usually still be obtained before any research procedure is contemplated. Details of the research procedure should be explained in terms capable of being understood both by the parent or guardian and by the child.

See also: Seeking parental consent for research involving competent children (below)

2.5.4 Assessing a child's competence to consent to participate in research

MRC guidance: While normally increasing with age, competence is considered not to depend primarily on age, but rather on the ability to understand and weigh up options. It can be influenced by the way information is presented – many children will be competent if information is presented in an appropriate way and they are supported through the decision-making process.

A child's ability to consent develops as he or she learns to make increasingly complex and serious decisions, which can be experience and/or age-related. For people to be able to have the capacity to take a particular decision they must be able to:

- Comprehend and retain information material to the decision, especially the consequences of having or not having any intervention.
- Use and weigh this information in a decision-making process.
- Reach and communicate a decision.

2.5.5 Seeking parental consent for research involving competent children

Even if the child is competent, it is still normally good practice to involve the family in the decision-making process. It is particularly desirable to obtain parental consent for younger children or for procedures that carry any risk or discomfort.

If the competent child specifically asks for the family not to be involved in the decision-making process and they cannot be persuaded otherwise, their privacy should be respected. (MRC guidance)

For children under 16 years of age […] 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. (BPS guidance)

As stated above in 'Seeking consent for research involving children under the age of 16', the Committee considers that even if an investigator believes that a child is capable of giving legally valid consent, the approval of a parent or guardian should usually still be obtained before any research procedure is contemplated. There may, however, be some situations that justify making an exception to this general rule, where research is worthwhile, does not present risks to participants, and seeking parental consent would not be possible. If researchers propose proceeding on the basis of the consent of participants under the age of 16 years, without seeking

the additional consent of their parents, the reasons for doing so must be clearly stated in the application.

2.5.6 Involving children in decisions to participate in research

Ethically it is important to involve children as much as possible in decisions about their own health, wellbeing and healthcare. The United Nations Convention on the Rights of the Child states that the child has a right to be informed, to express a view and to influence a decision. Methods used to facilitate the consent process should be appropriate to the age and understanding of the child. The Department of Health provides very useful guidance on consent for both patients and clinicians, including guidance for children and for parents/guardians explaining what they have a right to expect. (MRC guidance)

A person with parental responsibility may legally consent to treatment on an incompetent child's behalf. If the child is able to give assent to decisions about participation in research, the investigator must obtain that assent in addition to the consent of the legally authorised representative. If the child does not assent, this should be respected. (MRC guidance)

Therefore, children who are potential participants in research, whether or not they are competent to consent to participation, should be informed about what participation would involve. Depending on the age of the children, this may involve providing them with information sheets that use simple language and illustrations, or it may involve telling them what will happen and asking if that is acceptable.

2.5.7 Distress or avoidance of testing situations by children

Children and young people should not usually be involved in research if they object or appear to object in either words or actions, even if their parents consent. (GMC guidance)

When testing children, avoidance of the testing situation should be taken as evidence of withdrawal of consent/assent to the procedure and should be acknowledged as withdrawal from an investigation. Protocols should take this into account and testing should be discontinued and the child withdrawn from the study if he or she avoids participating in the testing situation. This is particularly important in research involving infants and very young children, who may be unable to verbalise distress.

Distress may also constitute withdrawal of consent/assent by a child. The Committee suggest that both the parent and the investigator should be able to terminate the procedure at any stage, for example if the child becomes distressed. They also suggest that the description of the research should establish the criteria which will lead the investigator to terminate the procedure, for example, whether the procedure will always be terminated if the child begins to cry, or whether crying will continue for a certain length of time before the procedure is terminated, etc. The Committee are reluctant to set out criteria themselves, since proposed criteria might be so stringent as to undermine some tests.

2.5.8 Consent for research based on school activities

Although a teacher acts *in loco parentis* on educational matters during school hours, in the view of the Committee this authority does not extend to participation by the children in research studies.

The Committee have no authority to regulate the way in which a head teacher deals with parents, but consent by the head teacher on behalf of parents is not acceptable; consent must be obtained by the investigator from the parents and, where appropriate and possible, from the child. In such circumstances the Committee will expect parents to be given the fullest possible information about the research before the activity takes place. This may be of particular importance if children are to be withdrawn from their usual lesson time in order to participate in the research.

In investigations studying the interactions between children and their peers, it is important that the consent of the peers' parents is obtained for the involvement of their children in the investigation, even though the peers themselves are not the subject of the investigation.

The Committee may be satisfied with passive (opt-out) consent, providing participants/parents are fully informed and have adequate opportunity to opt-out or withdraw their child from the research, particularly if the research is non-intrusive e.g. involves observation of the whole class engaging in an activity. Methods of informing parents must be independent of the children themselves. The justification for selecting an opt-out model for obtaining consent should be stated clearly in the application.

If an educational activity is taking place as part of the normal activities of a school, assessment of such activity as part of a research project will not, in the view of the Committee, require parental consent, although use of the results of the assessment might.

(See also 2.3.5 Recruitment: Permission from head-teachers etc. and Use of teachers to recruit children)

2.6 Confidentiality and data protection

2.6.1 Duty of 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. (BPS guidance)

If a breach of confidentiality is a possibility, it should be properly explained in the Information Sheet given to participants.

See also: Breaching confidentiality to protect individuals from harm (below).

2.6.2 Data security

The Committee agree that the researcher should take all reasonable steps to ensure that confidential information (information that could identify participants) does not inadvertently fall into the hands of anyone other than the research team. Electronic data should be stored on encrypted password-protected drives, confidential data on paper should be stored in a locked filing cabinet.

Confidential data will need to be stored for the duration of the study, and often for a period following publication, to allow verification of results and conclusions. In some circumstances, it may be necessary to store confidential data for longer periods (for example, it is considered good practice to retain the recordings on which certain forms of qualitative analysis of conversation or behaviour were based, to confirm credibility). The length of time it is proposed that confidential data be stored should be stated clearly on the application form, together with reasons for storing confidential data beyond the end of the study. Where participants could be identified from the data, their consent to its ongoing storage must be obtained.

2.6.3 Breaching confidentiality in the public interest or because of a legal obligation

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. (BPS guidance)

2.6.4 Suicidal intent or ideation

In studies involving the assessment of depressive symptoms, the Committee are concerned about what action the researcher will take in the event of a participant revealing suicidal intent or ideation. The Committee has agreed to suggest that the researcher should adopt the following course of action in the event of a participant revealing suicidal intent or ideation:

a) The researcher should provide the participant with advice concerning sources of help, and should encourage the participant to consult their General Practitioner. For web-based surveys, these resources should be provided in a prominent position.

b) The researcher should endeavour to obtain the participant's permission to inform the participant's parents (in the case of children) or General Practitioner (as discussed with the participant) of their suicidal intent or ideation.

c) If the participant refuses to grant permission for the researcher to inform someone of their suicidal intent or ideation, then the researcher should proceed to inform the participant's parents (in the case of children) or General Practitioner (as discussed with the participant) without consent.

If the researcher is concerned that the participant is in imminent danger of suicide or serious self-harm, then they should ensure that the participant receives the necessary medical attention, for example by calling 999.

2.6.5 Child safeguarding: duty to disclose information to third parties

If a researcher becomes concerned for a child's welfare and safety, he or she may be obliged by law to disclose information to the statutory authorities, and this should be made explicitly clear to participants before any face-to-face interviews take place. The potential break in confidentiality that would occur by disclosing such information should also be included in the Information Sheets given to participants. In the event that information that a child may be at risk of physical, sexual or emotional abuse, or of neglect, the researcher may encourage participants to disclose information to the statutory authorities, but must make clear to participants that the researcher will be obliged to disclose the information him or herself at the earliest opportunity.

2.6.6 Discovery of serious disability during tests

Although the research psychologist will normally respect the wishes of the participant, in certain extreme cases (for example, where a life is in danger) the psychologist has a duty, which overrides the duty of confidentiality to the participant, to inform a medical practitioner or parent of the need for treatment.

For example, for a submission studying driving after head injuries the Committee agreed: (a) that participants should be provided with information about how they had performed in a test of driving ability; (b) that if a participant performed so badly in the test as to demonstrate that he or she was a danger to himself or herself or to other road users, in the opinion of the investigator conducting the test and bearing in mind the limitations of the test period, the investigator should discuss with the participant whether the participant should consult a general practitioner; and (c) that the investigator should bear in mind his or her own responsibility if the participant declined to consult a general practitioner.

2.6.7 Publication, disclosure to third parties, and re-use of data in further research

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. (BPS guidance)

The absence of a person's name from a set of data obtained from participants (e.g. answers to questions) is not a guarantee of anonymity, since certain combinations of personal information

might uniquely identify a person. Unless explicit consent is obtained from participants for the release of personally identifiable information, every precaution should be taken to ensure the anonymity of participants in any data which is to be published, made available beyond the research team, or used in another research project.

The Committee requires that if any information that could foreseeably be used to identify participants is to be made available beyond the research team, then the investigators should state on the application form: (a) to whom this information will be made available; and (b) how the consent of participants will be obtained.

2.6.8 Questionnaires: anonymity and confidentiality

For studies involving the circulation of questionnaires, the Committee note that certain combinations of answers on anonymous questionnaires may be used to identify individuals. The Committee agree that the guarantee of anonymity is not the absence of the participant's name but the way in which the replies are safeguarded. Investigators should note that the absence of a name from a record does not necessarily exclude the data from the provisions of the Data Protection Act.

Where studies involve the circulation of questionnaires to students and the questionnaires ask participants to state their college affiliation, investigators should consider carefully any implications. In such cases the Committee may question the value of asking for college affiliation and may be dubious about the value of this information in relation to answers to the other questions.

For studies involving the circulation of questionnaires, the Committee agree that specific assurances should be given by the senior investigator or project supervisor about the safeguarding of data, and that the provisions of the Data Protection Act should be complied with.

2.7 Research associated with risk of harm or discomfort

2.7.1 Categories of research involving more than minimal risk

The BPS has identified the following psychological research as normally being considered as involving more than minimal risk:

■ Research involving vulnerable groups (such as children aged 16 years 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 requires approval via NRES.

The Committee recognises that such research may be worthwhile, but expects that the risks involved to be explicitly identified in the application (Q. 10), and that applicants will include their justification for proposing a protocol that could expose participants to more than minimal risks, and the measures they will take to minimise the likelihood or degree of harm occurring, and to mitigate the effects of any harm that does arise. Further guidance regarding some of these areas of research is given below.

2.7.2 Risk assessment and management

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. (BPS Guidance)

Applicants should assess potential risks to participants and include plans for managing any risks in the research protocol. As a general rule, the risk of harm should not be greater than in ordinary life. Any risks identified should be stated explicitly in the application (Q. 10), together with the plans in place to reduce or mitigate against them. Participants should be informed of procedures for contacting the investigator, should stress, potential harm, etc., arise.

2.7.3 Risk analysis

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. (BPS Guidance)

It was suggested to the Committee that the value of research should be assessed by some form of cost-benefit analysis, and that the rules to determine whether research should go ahead should be made explicit. The Committee recognise that individual investigators should consider such matters, but are of the opinion that no committee can be competent to assess the quality of research in all areas of psychology.

2.7.4 Research involving sensitive topics

For research relating to behaviour or experiences that participants may regard as personal and private, an explicit assurance should be given that answers to personal questions need not be given. The Committee agree that while it is difficult to define what constitutes a personal question, this principle will generally be understood by participants.

The Committee agree that if a structured interview is to take place, an interview schedule should be made available to the Committee, even if it is in draft, as otherwise it is difficult for the Committee to make an informed decision.

In relation to research projects concerned with child sexual abuse, the Committee have expressed concern that in some undoubted cases of child sexual abuse, the abuse may be concealed by participants from themselves and might take a substantial period of discussion to reveal. When dealing with issues such as this it may be considered unethical to allow a single discussion/interview to be conducted with participants for the purposes of research, unless long-term counselling/help is also available for participants who cannot 'open-up' or who 'open-up' too much in the research interview.

2.7.5 Research involving a significant element of deception

The Committee accept that a certain level of deception about the purpose of procedures may be necessary in some research projects. The Committee agree that the tests for the acceptability of deception should be: (a) that when the manipulation/deception becomes known it is unlikely to cause significant distress; and (b) that the deception is necessary for the purposes and conduct of the research. Debriefing should normally be conducted once testing has been completed.

Subliminal priming may constitute deception. Whether there should be debriefing of the participant about the fact that there was subliminal priming is dependent on the significance of the deception, and debriefing about subliminal priming will be required only if such subliminal priming is likely to create problems later for the participant.

2.7.6 Questionable or objectionable statements made in the course of tests

In a study of the development of gender difference in young children, a particular research tool (the CPAQ trait stereotype measure), appeared to make statements about sexual differences as statements of fact, for example that 'One of these kinds of people cries when they get hurt or when they are sad'. Some members of the Committee suggested that the combination of such statements with an indication of sexual differentiation between the 'kinds of people' and a forced choice between male and female in the test was unacceptable. The Committee noted that it was the combination of a leading statement and a forced choice that was unacceptable, and that certain parents, if they understood what kind of statements might be made, would object to their children taking part in the test, particularly since the test was to be conducted in the environment of a pre-school playgroup, where children would be used to being told certain things as facts by the playschool supervisors. The Committee agreed that they would prefer some modification of the test to eliminate this feature, but recognised that this might invalidate the test. The Committee also discussed whether this problem could be dealt with by debriefing, but agreed that debriefing pre-school children was not likely to be very satisfactory.

2.7.7 Mood induction

Participants who are already depressed, or may have had depression or other affective disorders in the past, may need to be protected from the possible harmful effects of negative mood induction. On one occasion the Committee asked the applicants concerned with a submitted research proposal if they were prepared to exclude certain types of participants. The investigators were also required to check the mood after induction of a positive mood at the end of the session, and to explain before mood induction what would take place. Appropriate counselling should be in place for studies involving mood induction.

2.7.8 Questionnaires: potentially offensive questions

Where questionnaires include questions that might foreseeably offend some people, then a letter should accompany the questionnaire which (a) gives participants an explicit and clear warning about the potentially offensive nature of some of the questions within the questionnaire and the responses required, and (b) advises participants that, if they think they might be offended by this then they should return the questionnaire to the researchers uncompleted.

2.7.9 Administration of pharmaceuticals or active compounds with physiological effects

All compounds licensed under the Medicines Act are included in this category. However, some products may be considered as investigational medicinal products (IMP) and studies involving them as clinical trials of investigational medicinal products (CTIMP), in which case NRES approval should be sought. If there is any ambiguity, investigators should contact the Medicines and Healthcare Products Regulatory Agency (MHRA, http://www.mhra.gov.uk/) for confirmation and any response included in the application.

For proposed research projects involving the administration of an active compound in venues other than hospitals or medically controlled set-ups, a medically qualified practitioner must always be immediately available in case of side-effects or medico-legal implications (in relation to, for example, idiosyncratic responses). Appropriate insurance must be in place for these studies; further information can be obtained from the Insurance Section: http://www.admin.cam.ac.uk/offices/insurance/

Clinical trials of investigational medicinal products (CTIMPs) must seek NRES approval.

There could be certain categories of persons who should not participate in investigations involving pharmaceuticals or other active compounds, such as those who know that they are particularly susceptible to the effects of the compound to be administered, or who have a health condition that it likely to be exacerbated by the compound or to make them particularly susceptible to its effects, those already taking these or other similar drugs (or drugs with which the compound administered might interact), or those with a history of anxiety disorders. Such persons should be excluded as early as possible; investigators should note the possible conflict that might arise if potential participants become aware that they might not receive any payment, if payment is proposed, if they exclude themselves by revealing such matters.

Investigators should also warn participants about the possible side effects of the administration of the proposed compound, such as effects on driving, the possible consequences of taking alcohol, etc.

Special arrangements are in place for studies involving the administration of active compounds. In particular, harm to participants as a result of the study procedures must be reported to the Committee as soon as possible, but within 5 days, of occurrence of the incident.

The Principal Investigator and anyone on the research team with direct contact with participants during the administration of the active compounds should have a current certificate of Good Clinical Practice.

2.7.10 Harm to participants during studies involving active compounds

Guidance on procedures that result in harm to participants as a result of administration of the active compound is derived from that offered by the School of Clinical Medicine.

Harm is defined as anything that results in harm or potential harm to participants, including violations or deviations of the study protocol (see below). It is also known as an Adverse Event or Serious Adverse Event, depending on the severity of what occurred to the participant.

As soon as investigators are aware of any harm to participants (as defined above) they should contact the Secretary to the Committee without delay who will advise on what documentation is required by the Committee. If there has been actual harm to participants, the study should be halted and not restarted until there is agreement from the Committee. Investigators should also contact their Governance Officer and the Insurance Section.

An investigation should then be carried out by the Head of the relevant department and a report submitted to the Committee within 15 days of the incident. The investigation should set out what has occurred and if necessary what steps are being taken to ensure that there is no recurrence of the incident. A further investigation may also be advisable involving someone independent of the original study.

2.7.11 Protocol violations and deviations during studies involving active compounds

A protocol violation is an intended departure from the expected conduct of the study. If it does not impact on subjects' safety or compromise the integrity of study data it is classified as non-serious or minor in nature and does not need to be reported to the Committee.

An urgent safety measure is an intended change of the protocol to eliminate an immediate hazard to participants. This can be undertaken by the Principal Investigator without prior approval from the Committee.

A protocol deviation is an unintended change to the protocol made without permission as a result of error, fraud or misconduct. If classified as non-serious or minor in nature it does not need to be reported to the Committee.

A Serious Protocol Deviation (i.e. a "serious breach" of a protocol) is a breach of protocol of the conditions or principles of Good Clinical Practice which is likely to affect to a significant degree the safety or physical or mental integrity of the participants, or the scientific value of the research. For example, failure to obtain informed consent, study procedures not approved by the Committee (unless for immediate safety reasons), dispensing or dosing errors.

If a serious protocol breach occurs the Principal Investigator should write to the Secretary of the Committee immediately, but within 5 days of the incident, indicating: when the breach occurred; the location; who was involved; the outcome and any information given to participants; and what action will be taken to mitigate subsequent occurrence. Again, investigators should contact their Governance Officer and the Insurance Section.

If an urgent safety measure is undertaken, the Principal Investigator should write to the Secretary of the Committee as soon as possible, but within 5 days of the incident, including when the measures were implemented; the location; who was involved; the reason for taking the measures; the outcome and any information given to participants; and what permanent action, if any, will be taken to mitigate the need for a similar urgent safety measure in the future.

2.7.12 Video recordings

The Committee requires that if any personally identifiable information is to be made available beyond the research team then the investigators should state in the application for ethical approval: (a) to whom this information will be made available; and (b) how the consent of participants will be obtained.

When investigators intend to use video recordings during research projects, they should inform the Committee in their application (a) whether the video material will be made available outside the research team (e.g. shown at talks or used for teaching), and (b) when the videos will be destroyed or how long they will be kept for.

2.7.13 Children: discussion of research results with parents and teachers

In research involving children, great caution should be exercised when discussing the results with parents, teachers, etc., since evaluative statements may carry unintended weight.

2.8 Research conducted online

BPS Guidance suggests that, while the same general principles apply to traditional psychological research and to internet-mediated research (IMR), IMR can raise particular, sometimes non-obvious challenges in adhering to existing ethics principles. These issues include: the public-private domain distinction online; confidentiality and security of online data; procedures for obtaining valid consent; procedures for ensuring withdrawal rights and debriefing; levels of researcher control; and implications for scientific value and potential harm.

Summary of the main ethics issues to consider when designing, implementing or assessing an IMR study (BPS Guidance):

Principle	Considerations
Respect for the autonomy and dignity of persons	Public/private distinction – The extent to which personal data derived from online sources should be considered in the public or private domain; Confidentiality – Levels of risk to the confidentiality of participants' data, and how to minimise and/or inform participants of these risks, particularly where they may potentially lead to harm; Copyright – Copyright issues and data ownership, and when permission should be sought to use potential data sources; Valid consent – How to implement robust, traceable valid consent procedures; Withdrawal – How to implement robust procedures which allow participants to act on their rights to withdraw data; Debriefing – How to implement robust procedures which maximise the likelihood of participants receiving appropriate debrief information.
Scientific value	Levels of control – How reduced levels of control may impact on the scientific value of a study, and how best to maximise levels of control where appropriate.
Social responsibility	Disruption of social structures – The extent to which proposed research study procedures and dissemination practices might disrupt/harm social groups.
Maximising benefits and minimising harm	Maximising benefits – How each of the issues mentioned above might act to reduce the benefits of a piece of research, and the best procedures for maximising benefits; Minimising harm – How each of the issues mentioned above might lead to potential harm, and the best procedures for minimising harm

2.9 Research conducted outside Cambridge

2.9.1 Research conducted outside the United Kingdom

Psychologists 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, psychologists 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. (BPS Guidance)

The Committee will consider applications for approval of research that will be conducted outside the UK, provided that the principal investigator or supervisor is affiliated to a Cambridge University institution or department or an MRC Unit in Cambridge. Investigators must provide written authorisation or formal invitation to undertake studies from the relevant host country or countries.

Investigators should demonstrate that the research will be conducted to the same high ethical standards required of research conducted in the UK. However, it is accepted that some practices considered standard in one culture or context may need to be adapted to make them appropriate and acceptable to participants in another culture or context. Reasons for diverting from standard practice should be included in the application.

2.9.2 Research that has received ethics approval from another REC

Where research is to be conducted in more than one centre or country, the protocol may have already received ethical review. The Committee may be prepared to accept the approval of another REC, provided that it is properly constituted to review the research and operates to a similar standard to that required in the UK.

A copy of the application and decision should be submitted to the Secretary of the Committee, for scrutiny by the Chair in the first instance.

2.10 Research involving children or young people

2.10.1 Involving children in research

Research involving children and young people can benefit all children; but they may be vulnerable because they cannot always recognise their best interests, express their needs or defend their rights. Children or young people should be involved in research only when research on adults cannot provide the same benefits. They can be involved in research that has either:

a. potential benefits for children or young people generally, as long as the research does not go against their best interests or involves only minimal or low risk of harm (this would be research that involves, for example, asking questions or taking blood samples, the assessment of the risk depending on the view of the child or young person), or

b. potential therapeutic benefits for them that outweigh any foreseeable risks, which should be kept as low as possible. (GMC guidance)

The Committee consider that the application of this rule is not straightforward in developmental psychology. The Committee would consider research to be ethical, for example, where information is collected about one stage of human development that is relevant to a later stage, or where the results of the research will be of benefit to children generally but only at a later stage of their lives.

2.10.2 Safeguarding children: checks for researchers

Researchers, including research assistants and students, who will be directly involved in research involving children or young people (testing or interviewing) should undergo appropriate checks with the Disclosure and Barring Service (DBS) which replaces the Criminal Records Bureau (CRB) check required prior to December 2012.

See also sections on Confidentiality data protection, Consent: children and young people, Research associated with risk of harm or discomfort.

2.11 Supervision

2.11.1 Projects conducted by students or Research Assistants

The Committee expect that submissions for research projects which will be carried out by research students or research assistants (or comparable persons) will be submitted jointly with some more senior person, such as the supervisor.

All investigators in a research project have responsibilities for ethical standards and for the observation of any conditions imposed by the Committee and therefore they should all be named as co-applicants in point 1 of the application form, together with their appointments or positions and qualifications, and they should all sign the application form.

In some undergraduate projects, the supervisor may design the protocol and apply for ethical approval before a student is assigned to the project. In this case, the student's signature will not be required.

2.11.2 Student research projects: supervisor in Cambridge required

The Committee agree that they will not give ethical approval to a submission from a research student where the supervisor, named on the application form is not working in Cambridge as a member of the staff of a University department, college or MRC unit.

2.11.3 Applications for research projects forming part of departmental teaching programmes

The Committee expect that any application relating to a research or investigation project which forms part of a taught course will have been discussed with the Head of Department concerned before submission. Copies of all letters from the Committee relating to such applications will be sent to the Head of Department concerned. The Committee agreed that this will apply to taught components of all courses of instruction, and not solely to undergraduate courses.

2.12 Other considerations

2.12.1 Institutional affiliation of applicants

The Committee require that the principal supervisor of any project put forward for ethical approval should be affiliated to a Cambridge University institution or department or an MRC Unit in Cambridge.

2.12.2 Scrutiny of research projects before submission

It is for departments/units to decide on internal procedures to determine what range of projects should be referred to the Committee. Some might fall outside the scope of psychology while others would raise no ethical issues. The Committee recommend that a decision on whether to refer a project to the Committee should not be taken solely by the initiator of the research, and that whenever there is doubt about whether an ethical issue exists, the project should be referred to the Committee.

2.12.3 Pilot studies

The Committee agree that pilot studies which raise ethical issues can be submitted for ethical approval. The Committee agree that if pilot studies raise ethical issues, the fact that such a study is a pilot study does not affect the issue of whether the proposal should be submitted for consideration of the ethical issues. They also agree that they will accept an account of the methodology which will allow some flexibility in a pilot study.

Studies that include a pilot phase, during which the suitability of a variety of measures will be tested, and a second phase, during which the most suitable measure will be used to gather data, can be submitted for approval. Details of all the measures to be piloted should be included with the application. Prior to commencing the second phase, the investigator should inform the Committee of the measure that has been selected for use.

2.12.4 Ethical review before submission for funding

Ethical approval has been sought from the Committee for proposals presented in the form of research grant applications in order that the applications can be submitted for funding. The Committee agree, in principle, that ethical approval can be given in such cases, subject to subsequent submission of details of the procedures to be adopted and approval of these by the Committee. The Committee would be prepared to state, for such preliminary applications, that they do not envisage any particular difficulties over ethical issues which cannot be resolved.

The investigator concerned will be able to submit the letter from the Committee to Research Councils, etc., in fulfilment of any requirement of the Research Council for adjudication of the research project by an Ethical Committee.

Nonetheless, the source of funding may potentially create a conflict of interest that compromises the research. Ethical approval granted before funding is secured should be regarded as provisional, and information about the source of any funding obtained should be submitted to the Committee before research begins.

2.12.5 Alterations to research projects

Ethical approval of the project will relate to the project as submitted and as described in the documents before the Committee. If amendments are later made to the research project, for example because of comments by Research Council referees, it will be a matter for the investigator concerned to decide whether the changes invalidate the ethical approval previously given. Similarly, if new ethical issues are raised by the development of research, it will be for the investigator to decide whether to resubmit the project (see Section 1 – Procedure).

2.12.6 Follow-up of approved research projects

Investigators should inform the Committee of any unforeseen ethical issues that arise during the research.

The Royal College of Physician's guidelines (RCP Guidelines/Ethics Committees, section 7.8) refer to the need for an ethical committee to follow up the research proposals submitted. This arises in the context of clinical medical research largely in drug trials, and the aim of this requirement is to ensure that clinical research is included in patients' records and also to ensure that certain patients are not over-researched. The Committee agreed that they would not institute a follow-up procedure for submissions made to the Cambridge Psychology Research Ethics Committee.

2.12.7 Arrangements for participants found to be in need of help or treatment

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. (BPS guidance)

If participants in need of help or treatment (for either medical/physiological or psychological reasons) are found during research, then investigators have a general responsibility to indicate to such participants that they should seek assistance, and also to indicate how that assistance may be obtained.

The Committee agree that ethical approval of a proposed research project may be subject to a satisfactory statement being made by the applicants concerning the help that will be offered if psychological problems are disclosed during interviews.

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. (BPS Guidance)

The Committee consider that it is inappropriate for investigators or research staff to become involved in the clinical treatment of participants, and agree that investigators should direct participants who require treatment or help to the relevant services, such as the participant's General Medical Practitioner.

The Committee do not consider it to be appropriate for investigators either to refer participants for counselling, or to provide counselling themselves. However, in the event of the need for counselling being perceived, the investigator should give participants advice on sources of counselling.

If an investigator notices any signs of illness in participants, then the Committee expect that the investigator will help those participants get the evaluation or treatment required by advising them to get in touch with their General Medical Practitioner or other source of help, as appropriate. However, the Committee agree that, where an investigator is not medically qualified, care should be taken not to raise unrealistic expectations in participants about the nature of the research and the abilities of the investigator to detect illness. Therefore any written information supplied to participants should *not* contain any statement or claim concerning the investigator's abilities to detect illness; such as 'if we notice any signs of illness in your child, we will inform you and help you get the evaluation or treatment your child needs'.