Ethics and physiological testing.

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CHAPTER 4

ETHICS AND PHYSIOLOGICAL TESTING

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WHAT IS ETHICS?

What is it to behave in an ethical manner as a researcher? The term 'ethics' suggests a set of standards by which behaviour is regulated, and these standards help us to decide what is acceptable in terms of pursuing our aims, as well as helping us to distinguish between right and wrong acts. The principal question of ethics is 'What ought I do?'

Broadly speaking, ethical actions are derived from principles and values, which are in turn derived from ethical theories. The major ethical theories are briefly introduced here for two reasons: to enable researchers to identify where principles are derived from, and to facilitate deeper thought on how potential actions may be justified.

Virtue theory focuses on being a 'good' person, and doing the right thing (e.g. being fair, honest and so on) necessarily flows from being a 'good' person. Utilitarian (consequential) theory attaches primary importance to the consequences of actions – if the 'good' consequences outweigh the 'bad' ones for all concerned by the action, then the action is right and is morally required. Lastly, Deontology holds that primacy is attached to meeting duties and obligations, that the ends do not justify the means, and that an individual's preferences, interests and rights should be respected. It is worth noting that codes of ethics are generally deontological in nature.

There are three basic principles upon which our conception of research ethics is based, namely respect for persons, beneficence (doing good) and jus- tice. Applying these to research contexts involves consideration of autonomy (an individual's right to self-determination), obligations not to harm others (including physical, psychological or social harm), utility (producing a net balance of benefits over harm), justice (distributing benefits and harms fairly), fidelity keeping promises and contracts), privacy, and veracity (truthfulness). More specific ethical considerations would include recognition of cultural

factors, preserving participant anonymity (or confidentiality, as appropriate), non-discrimination, sanctions against offenders, compliance with procedures and reports of violations (Olivier, 1995).

INFORMED CONSENT

A central feature of modern biomedical research ethics is the notion of obtaining first person, written, voluntary informed consent from research participants. Given that it is a required element of most projects, researchers need to be aware of what the concept involves.

First, 'informed' implies that potential participants (or their legal representatives) obtain sufficient information about the project. This information must be presented in such a way that it is matched to the appropriate comprehension level (see Olivier and Olivier, 2001; and Cardinal, 2000, for further details on establishing comprehension levels), enabling participants to evaluate and understand the implications of what they are about to agree to. Second, 'consent' implies free, voluntary agreement to participation, without coercion or unfair inducement.1

Consent can be considered to be informed when 'it is given in the full, or clear, realization of what the tests involve, including an awareness . . . of risk attached to what takes place' (Mahon, 1987, p. 203). Further, 'Subjects must be fully informed of the risks, procedures, and potential benefits, and that they are free to end their participation in the study with no penalty whatsoever' (Zelaznik, 1993, p. 63).

Consent is deemed ethically acceptable if the participant receives full disclosure of relevant information, if the implications are understood, if the participant voluntarily agrees to participate, if opportunities to freely ask relevant questions are present throughout the duration of the project and if the participant feels able to withdraw from the procedures at any time.

The informed consent form

The informed consent form, normally signed by the participants, should be tailored to the specific project that it relates to. The document should include the following elements:

- an explanation of the purposes of the project;
- a description of the procedures that will involve participants, including the time commitment;
- identification and description of any risks/discomforts, and potential benefits that can reasonably be foreseen, as well as any arrangements for treatment in the case of injury;

- statements regarding confidentiality, anonymity and privacy;
- identification of an appropriate individual whom the participants can approach regarding any questions about the research;

- a statement that participation is voluntary, that consent has been freely obtained and that participants may withdraw at any time without fear of sanction.

A consent form should not include language that absolves the researcher from blame, or any other waiver of legal rights releasing, or appearing to release any- one from liability (Liehmon, 1979; Veatch, 1989). The consent form should conclude with a statement that the participant has read the document and understands it, and should provide space underneath for a signature and the date. Space should also be provided for signatures of the researcher and an independent witness.

Written consent is considered to be the norm for all but the most minor of research procedures. It can serve to protect participants as well as investigators, and serves as proof that some attention has been paid to the interests of the participants. Written consent is superior to oral in that the form itself can be used as an explanatory tool and as a reference document in the communication process between researchers and participants. Also, presenting information orally as well as in written form may have the advantage of prompting participants to ask relevant questions. However, when there are doubts about the literacy level of participants, oral information should supplement proxy2 written consent.

Witnessed consent may be particularly useful when participants are elderly or have intellectual or cultural difficulties in speech or comprehension. In these cases, an independent person, such as a nurse or a community/religious leader, should sign a document stating that the witness was present when the researcher explained the project, and that in the opinion of the witness, the participant understood the implications of the research and consented freely.

Special legal or institutional considerations may apply when the research involves, inter alia, pregnant women, foetuses, prisoners, children, wards of the state or when deception is used. Research requiring deception, or procedures carrying an unusually high risk of harm, will typically require that a researcher satisfies additional conditions.3

There is little unanimity concerning the practice of paying research participants, particularly when intrusive procedures are involved. Researchers should be satisfied that payment does not constitute coercion, and remuneration should not adversely affect the judgement of potential participants in respect of risk assessment. Statements on payment to participants should not deflect attention away from the other information in the informed consent form.

Obtaining informed consent at the start of a project may not be sufficient – circumstances may change and new ethical considerations might arise4 – and researchers should be aware that consent with participants might

have to be renegotiated. This might also mean that emergent issues are referred back to the original ethics committee for clearance. It is worth noting that obtaining informed consent does not ensure that a research project is ethical. The research itself must be ethical, and researchers should consider the moral issues that apply to their work.

Children as research participants5

When utilising children as research participants, you should consider not only their rights to choose to participate in research (and to withdraw), but also issues such as power differentials, and coercion, in the recruitment process. If you are using a gatekeeper for access (such as a coach, or teacher), that person should not recruit children on your behalf, and should not have access to any individualised data collected. Beware of obtaining proxy consent, as it is unlikely that anyone in a relatively low hierarchical position (such as pupils in a school) will refuse to participate if someone higher up (e.g. a teacher, or Head) gives permission on their behalf (Homan, 2002). You should obtain active rather than passive (assumed) consent. Passive consent involves making the assumption that non-refusal constitutes tacit agreement to participate. While this is a much easier method of recruiting, it may disregard the autonomous wishes (or voluntariness) of participants.

The Medical Research Council (2004) supports the use of children in research as long as the benefits and risks are carefully assessed. Where there is no benefit to child participants, the risk needs to be minimal (see MRC, 2004, pp. 14–15 for categories of risk). Minimal risk activities include questioning, observing and measuring children,6 and obtaining bodily fluids without invasive intervention. This rules out more invasive procedures such as muscle biopsies.

In England and Wales, anyone who has reached the statutory age of majority (eighteen years) can consent to being a research participant in therapeutic or nontherapeutic7 studies. For therapeutic research, the Family Reform Act 1969 provides that anyone over 16 can provide consent. Below 16, it is suggested that no one under 12 can provide individual consent (rather than assent, it should be noted), but that children over 12 can provide consent if they are deemed sufficiently mature by the researcher (Nicholson, in Jago and Bailey, 2001). For nontherapeutic work, there is no precise age below 18 at which a child acquires legal capacity, but again, for anyone over 12, an assessment of maturity must be made. The problem with this, of course, is that researchers must 'accept the possibility of prosecution if their interpretation of a child's competence to consent is deemed unacceptable' (Jago and Bailey, 2001, p. 531).

Given that most research by BASES members is nontherapeutic, what should you do? For participants under eighteen, obtain parental consent, first person consent from the participants, and proxy consent from a relevant authority figure if appropriate. If your potential participants are aged 7 to 12, obtain assent (acquiescence, or yea saying) on a simplified form, as well as parental and proxy consent as appropriate. In all cases, the language used on consent and assent forms should be tailored to the participants' comprehension

levels (see Olivier and Olivier, 2001).

The ethics review process

The emphasis on research ethics in recent decades is a response to abuses perpetrated on human research participants in the past. This chapter is not the

place to enumerate such details (see McNamee et al., 2006), but suffice to say that the regulatory response has been to create a system of ethical review with which investigators must comply.

All funding bodies will insist, as part of the review process, that potential projects are carefully scrutinised with regard to ethical implications. Regulations in the United Kingdom are not as consistently applied as in the United States, but nevertheless, most institutions (e.g. universities, laboratories) will require formal approval of a project before data collection can proceed. Even for unfunded projects, submitting a project for ethical review has benefits for participants (protection of their rights, safety) and for researchers (evidence of compliance with proper procedures, rigour of study design). So, while some researchers view formal ethics review as a bureaucratic impediment to con- ducting research, it is deemed to be a valuable (if somewhat flawed) process that protects individuals and facilitates good science (Olivier, 2002).

Given that systems of ethics review vary from institution to institution and across funding bodies, it is important for the individual researcher (or team leader) to ascertain what the obligations are with regard to ethics review and compliance. Also, research managers need to be conversant with broader regulatory systems such as the Department of Health Research Governance Framework, NHS Local Research Ethics Committees and the recent introduction into UK law of the European Clinical Trials Directive (see McNamee et al., 2006).

Codes of conduct and accreditation

Codes of conduct and accreditation schemes, such as those administered by BASES, are particularly useful in terms of promoting and maintaining professional competence. A code of conduct though, while promoting ethical behaviour, does not ensure it. This is because rules can conflict, because they are not exhaustive of all moral situations, because they may not take consequences of actions into account, and because they don't consider important contextual issues. Further, if rules are very specific you need an inordinate number to cover all relevant situations, and if they are general then they are likely to be of little practical use. Lastly, and perhaps most importantly, simple rule-following is mechanical, and doesn't promote moral engagement.

Researchers should adhere to the requirements of the BASES Code of Conduct, but should also carefully consider the specific ethical issues that arise from their own projects. It is incumbent on individual researchers, as human agents of moral decision-making, to personally and carefully consider ethical issues inherent in their projects, and to analyse, evaluate, synthesise and apply appropriate principles and values.

Checklist

The checklist below is designed to assist you in preparing your project for ethical review. Remember though that projects are different, and encompass

a variety of ethical issues. The checklist is just a start. The challenge for all researchers is to think independently about the ethical issues presented by their work.

- Make sure that you get voluntary, written first-person informed consent. If this is deemed inappropriate, you need to justify the exception.
- Check institutional or legal guidelines about parental consent, and about obtaining a child's assent. In the case of using children as research participants, obtain the necessary parental consent, and the child's assent.
- When using vulnerable populations (e.g. the aged, wards of the state or other agencies), check that you comply with any ethical requirements specific to that group. For example, you may need witnessed consent for cognitively impaired participants.
- Satisfy yourself that participants understand the nature of the project, including any risks or potential benefits. Describing the project to them verbally will often assist in this process.
- Explain to participants that they are free to ask questions at any time, and that they can withdraw from the project whenever they want to.
- Make sure that no coercion occurs during the recruitment process. (Here you need to be clear on issues such as the researcher not being a teacher or assessor of participants' work, for example in the case of students.)
- Allow participants a 'cooling off' period to consider their participation (the time between reading the form and actually agreeing to take part).
- Assess the risk of physical, psychological or social harm to participants.
- Provide medical or other appropriate backup in the event of any potential harm in the categories mentioned earlier.
- Provide medical or other screening, as appropriate.
- Assess the risk of harm to yourself as a researcher, and any assistants (e.g. handling of body fluids, or personal safety in interview situations).
- Provide for the safe conduct of the research if anything has been identified in the preceding point (e.g. correct laboratory procedures; protection in interviews; ability to contact emergency services).
- Assess the impact of any cultural, religious, or gender issues that may pertain to your participants, and/or the dissemination of your findings.
- Provide adequate assurances regarding privacy, confidentiality, anonymity, and how you will securely store and treat your data.
- Satisfy yourself that any payments or inducements offered to participants do not adversely influence their ability to make an

informed assessment of the risks and benefits of participation.

- Satisfy yourself that any funding or assistance that you receive with the research will neither result in a conflict of interest, nor compromise your academic integrity.
- If your study involves deception, state the reasons/justification, and indicate how you will debrief the participants about the deception.
- Set measures in place to provide participants with feedback/information on completion of the project.
- And of course, make sure that you have received approval to proceed from the appropriate regional, national or institutional ethics committees.

NOTES

1. I recognise that that this reduction of the concept of informed consent is simplistic, and begs the fallacy of composition (Morgan, 1974), which is the notion that one can break down complex terms into their constituents and then merely add them up as if the sum of the parts was equal to the whole. Nevertheless, it is a useful starting point for the practical application of informed consent procedures.
2. Proxy consent is consent given for an individual, by someone else, for example a parent, religious leader, etc. When seeking proxy consent, particular care should be taken to consider the issues surrounding autonomy and paternalism (see McNamee et al., 2006).
3. For example, justification for deception would include that the research is important, that the results are unobtainable by other methods, that participants are not harmed, and that thorough debriefing occurs if appropriate.
4. Such as the application of new measurement procedures, for example.
5. I would like to thank Malcolm Khan, Senior Lecturer in Law at Northumbria University, for commenting on the legal accuracy of this section.
6. Such activities must be carried out in a sensitive way, with due consideration given to the child's autonomy.
7. I recognise the difficulties with this distinction in terms of describing medical research, but feel that is still useful in terms of much of the research conducted by BASES members.

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