Proportionality of risk and the making of sound ethical decisions in human research

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Key Question: How might researchers make sound ethical decisions in human research?

Consider the case of a researcher who wishes to use deception in her study. She wants to lie to her subjects, to get them to believe that X is the case (when in fact it is not), in order to assess their responses. And believing that X is the case induces quite high levels of stress in the participants. But even though we might believe it is wrong to lie and to place others under unnecessary stress, the outcomes of this study could be widely beneficial to many.

The procedures of the study appear to violate principles that we believe to be right, but the good that could come out of the study might justify the suspension of those principles. Often the most intractable ethical issues in research arise out of such conflicts: conflicts that appear to be between what is 'right' and what is 'good'.

In assessing the ethical integrity of a research study, we are often led to a consideration of whether the degree of violation of principles that we believe to be right justifies the amount of good that could follow the study as a consequence. The question is often, "Is the degree of risk (say, in inducing these levels of stress) worth it when we consider the beneficial outcomes that could be consequent on this study?" This issue of *proportionality of risk* lies at the heart of many of the more difficult questions in the ethics of research.

In response to these questions and issues, this session will introduce you to two different approaches to making ethical decisions: consequentialist ethics, and non-consequentialist (or deontological) ethics.

Two approaches to thinking about ethics:

1. An approach that focuses on consequences and tries to maximize the good in its search for the best outcomes. This is known as **Consequentialist Ethics**.

2. An approach that focuses on the duty to uphold the principle of what is right, irrespective of consequences. This is known as **Non-consequentialist Ethics** or as **Deontological Ethics** (from the Greek word *deon*, meaning *duty*).

Consequentialist ethical theories and Non-consequentialist (or Deontological) ethical theories are two of the most well-known and established paradigms within which to think about ethics.

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Consequentialist Ethics

"Consequentialist ethical theories hold that the morality or immorality of an action is to be determined by its consequences".

That is, "right conduct is that which maximizes the good".

So consequentialist ethical theories depend on our knowing the consequences of our actions and on our being able to being able to compare different sets of possible consequences in order to ascertain which would be best.

Problems with Consequentialism:

1. The difficulty of knowing the consequences of our actions and their impact on everybody concerned.

2. The difficulty of determining which consequences would be best.

3. Utilitarianism can produce consequences that seem morally unacceptable: for example, the greatest good for the greatest number could be achieved by seriously exploiting a comparatively small number of research participants.

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Nonconsequentialist/Deontological ethics

Nonconsequentialist ethics emphasise ethical principles, obligations, and duties, over the consequences of actions.

Nonconsequentialist ethics are also known as deontological ethics
(from the Greek, *deon*, meaning *duty*)
(deontological = concerned with duty or moral obligation).

Immanuel Kant's (1724-1804) "categorical imperative", or absolute moral command:

You should act so that the principle that guides your behaviour should be treated as a universal rule of human conduct.
For example, do not lie, because the principle of telling the truth (which guides your behaviour) is a principle that should be treated as a universal rule for all human conduct.

For a moral rule to be universal, it means that
      - there are no exceptions;
      - it is applied impartially;
      - it is applied consistently.

Kant's categorical imperative suggests that the test of our actions lies in whether we are willing to have the same moral standards applied to us as we apply to others. Hence his so-called Golden Rule:
      "Do unto others as you would have them do unto you".

This assumes the treatment of people as ends rather than mere means: that we respect people as beings with intrinsic worth.

Note, very importantly, that the ethics of research are most commonly based on ethical principles that recognize primarily the importance of the deontological perspective: that we respect each other as persons.

A *Problem with Deontological ethics:*

It's too easy to keep your hands clean. It's much more difficult to get your hands dirty and really wrestle with the difficulties associated with a particular moral difficulty.

Research Ethics

Principles Guiding the Ethical Integrity of Research

❑ **General Principles**

1. Integrity

The ethical integrity of research implies that the conduct of all researchers is characterized by a *respect* for self and others, a willingness to accept *responsibility* for the consequences of one's decisions, and by the principles of *goodness*, *rightness*, *fairness*, and *honesty*.

A *respect* for others implies that researchers accord appropriate respect to the rights, dignity, and worth of all researchers and subjects involved in the research.

2. Competence

Researchers should undertake only such research that they and their fellow researchers and research students are competent to, so that the safety of all research participants, and the ethical integrity of the research, might not be compromised for reasons of incompetence.

3. Professional and Scientific Responsibility

Researchers should conduct their research in a professionally and scientifically responsible manner. Such responsibility is commensurate with the ethical integrity of the research. Researchers should accordingly design, conduct, and report research in accordance with recognized principles and standards of scientific competence and ethical research, taking care, for example, to avoid plagiarism of any sort, whether in the use of others' data or findings, or in the reporting of their research.

4. Social Responsibility

Researchers should be aware of their professional and scientific responsibilities to the community and the society in which they work and live, and to the human community in general. Researchers should in their research seek to advance not only the science of their discipline, but also, ultimately, human welfare.

5. Concern for Others' Welfare

Researchers should, at all times and above all other research priorities, be concerned with the welfare and interests of those participating in the research. Researchers should thus take reasonable steps to implement appropriate protection for the rights and welfare of research participants and other persons affected by the research.

6. Proportionality of Risk

Research involving human subjects should not be carried out unless the importance of the objectives is in proportion to the inherent risk to the subject. Potential hazards should be predictable, and should never outweigh the benefits of the research.

❑ **Research-Specific Issues**

1. Informed Consent

Researchers should obtain the appropriate informed consent of research participants, in language that is reasonably understandable to research participants, and that is appropriately documented.

2. Inducements

Inducements to participate that are offered to potential research participants should be appropriate and commensurate with standard practice.

3. Deception

Researchers should not conduct a study involving deception unless they have determined that the use of deceptive techniques is justified by the study's prospective scientific value, and that equally effective alternative procedures that do not use deception are not feasible. Researchers should never deceive research participants about significant aspects that would affect their willingness to participate, such as physical risks, discomfort, or unpleasant emotional experiences. If deception is used, researchers are obliged to debrief subjects on the nature of the deception as soon as is practically possible.

4. Invasiveness

Researchers should ensure that any invasive procedures are kept to a minimum, and involve minimal discomfort and no physical or other risk to research participants.

5. Commitments

Researchers should take reasonable measures to honour all commitments they have made to research participants.

6. Sharing Information

Researchers should provide a prompt opportunity for participants to obtain appropriate information about the nature, results, and conclusions of the research.

7. Privacy and Confidentiality

Researchers should at all times seek to respect the privacy of research participants, and to maintain confidentiality in all matters related to individual research participants.