

These materials were developed for a course in International Bioethics offered in early 2012 as part of the Advanced Certificate Program for Research Ethics in Central and Eastern Europe, a collaborative project between Union Graduate College and Vilnius University. They are free for use, distribution and modification with proper attribution.

International Research Ethics 2

Week 1: Conceptual and Regulatory Aspects of Human Subjects Research

INTRODUCTION

An understanding of the ethical issues raised by social science methods is important for three reasons. First, many biomedical research projects use social science methods as part of their data collection. There are for instance many randomised controlled trials that involve questionnaires or the use of psychometric scales (e.g. quality of life scales). Second, there are many research questions in health care that can only be answered by doing research that is best described as social science research. We might, for instance be interested in knowing why a certain group does not use condoms when having sexual intercourse, or in knowing why medication errors arise in a specific context and both of these questions will have to be answered not by biomedical but by social science research. Third, there is a move in many countries to establish some kind of formal ethical review of social science research outside of the health care setting, either by setting up specific research ethics committees handling non-health care research or by other means of governance.

Social science methods are often used by researchers who are not themselves social scientists. Most social science methods or projects do not raise issues that are qualitatively different from biomedical research. The same considerations concerning risk, benefit, vulnerability and consent apply.

But some social science methods raise issues that are rare in biomedical research. These include observational research, research that is done covertly, and research involving deliberate deception. Others raise issues that occur in biomedical research with some frequency but which are not often problematised. These include problems related to cluster randomisation procedures and problems related to the psychological distress that can be caused by questionnaires and interviews on sensitive topics. This week we are going to look in general at social science research and more specifically at open and covert observation and at distress caused by data collection.

Observation is an important social science research method. We know that what people say they do or will do is not always what they actually do, and that the difference between reported behaviour and actual behaviour is larger if the behaviour is generally

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seen as unacceptable. Observation can be crucial in getting an accurate understanding of what actually happens in health care settings. Observational studies can be categorised in many ways, but the distinctions that are most important for the ethical evaluation are:

- Observation in public spaces versus observation in private spaces;
- Observation where the observer is a participant in the action versus observation by a non-participant observer;
- Observation which is open versus observation which is covert; and
- Observation with explicit consent from all those observed versus observation without consent from everyone.

These distinctions intersect in various ways. It is for instance quite possible to have completely open observation without obtaining consent from everyone who is observed. A researcher might, for instance want to study the flow of patients through a busy accident and emergency department and put up big and visible posters many places in the department, but still not seek to get the explicit consent from every single patient, relative and staff member.

The form of observation that is generally believed to be the most ethically problematic is covert or hidden observation where those who are observed do not know that research is taken place. This can involve the researcher being present without revealing the data gathering that is taking place, or it can involve the use of remote data gathering, for instance with video cameras. Although covert observation is in general somewhat ethically problematic there are still distinctions to be made. Covert observation in truly public spaces is, for instance often less problematic than covert observation in private or intimate spaces.

The mere act of data collection through a questionnaire or an interview can cause psychological distress if the data that are being sought are about sensitive matters or traumatic experiences. Such distress is often transient, but even transient distress constitutes a harm to the person who is distressed. This means that the risk of causing distress has to be minimised and that the researcher need to have a plan for how to respond adequately to any distress that might occur (it is not sufficient to rely on the participants right to withdraw).

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LEARNING OBJECTIVES

At the end of this week, students will be able to:

1. Define social science research, observational research, covert research, and deception;
2. Describe the main ethical issues raised by social science research methods in general;
3. Compare and contrast the ethical issues raised by open and covert observational research;
4. Explain the concept of psychological distress and describe solutions to minimize or mitigate distress; and
5. Develop solutions for reducing the risks to research participants when designing or reviewing a social science study.

TOPICS

1. General ethical problems in social science research;
2. Observational research;
3. Covert research;
4. Distress caused by research participation; and
5. REC review of social science research.

REQUIRED READINGS, AUDIO AND VIDEO

1. Petticrew M, Semple S, Hilton S, Creely KS, Eadie D, Ritchie D, Ferrell C, Christopher Y, Hurley F. (2007).(2007). Covert observation in practice: lessons from the evaluation of the prohibition of smoking in public places in Scotland. *BMC Public Health* 7: 204. Available online at <http://www.biomedcentral.com/1471-2458/7/204>.
2. Robson E. (2001). Interviews Worth the Tears? Exploring Dilemmas of Research with Young Carers in Zimbabwe. *Ethics Place & Environment* 4: 135-42. Available online at <http://www.utoronto.ca/~kmacd/IDSC10/Readings/Ethics/carers.pdf>.
3. UK Economic and Social Research Council. (2010). *Research Ethics Framework*. Swindon, UK: ESRC. Available online at http://www.esrc.ac.uk/images/Framework_for_Research_Ethics_tcm8-4586.pdf.
4. International Sociological Association (2001). *Code of Ethics*. Madrid, SP: ISA. Available online at http://www.isa-sociology.org/about/isa_code_of_ethics.htm.

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OPTIONAL READINGS, AUDIO AND VIDEO

1. Haggerty KD. (2004). Ethics Creep: Governing Social Science Research in the Name of Ethics. *Qualitative Sociology* 27: 391-414.
Available online at http://home.earthlink.net/~irbwatch/index_files/Haggerty04.pdf

DISCUSSION FORUMS

The Discussion Forums are the main vehicle for promoting interaction among the students. All students are expected to participate in each Discussion Forum by answering questions, challenging assumptions, posing new questions, and sharing concerns and insights. Timely participation is expected, as each Forum will remain active for only a two-week window.

Forum 1.1: THE UK ECONOMIC AND SOCIAL SCIENCE RESEARCH COUNCIL RESEARCH ETHICS FRAMEWORK (40 points).

The UK Economic and Social Research Council Research Ethics Framework is the main document governing research ethics governance of social science research in the UK (in the required readings). On pages 9-10, the Framework defines some types of social research that must always be given full scrutiny by a REC.

- Would all of these types of research go before a REC in your country?
- Do you agree with the ESRC about the types of research identified? Have the ESRC included too many? Has the ESRC missed any out that should have been included?

Forum 1.2: COVERT RESEARCH IN HEALTH CARE SETTINGS (30 Points).

Deliberately covert research is most often used in contexts where the population studied is powerful and the behaviour of interest is ethically or legally questionable, but may also be used if knowledge of the observation taking place would change behaviour. For example, covert observation has been used to evaluate the effectiveness of hand washing policies in hospitals. This has been done using participant observation, i.e. one of the staff members is covertly observing the others and by covert video observation.

- Is this research ethically acceptable? What are the arguments for its acceptability and what are the arguments against?
- Should this research be approved by a research ethics committee that applied the Helsinki Declaration or the CIOMS guidelines?

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Forum 1.3: THE HANDLING OF DISTRESS IN THE RESEARCH CONTEXT (30 Points).

A researcher is interviewing persons who have previously been admitted to hospital after suicide attempts. She is interested in understanding the context in which the suicide attempt was carried out, the set of events leading from the suicide attempt to the admission to hospital, and the support offered after discharge. Persons have been identified in hospital records and a letter then sent to them informing them about the project. Only persons who have actively responded that they are willing to be interviewed are being recruited.

- How should the researcher handle any distress that might be caused?

Forum 1.4: COMMENTS OR QUESTIONS (Optional).

WRITING ASSIGNMENT

There is no written assignment this week.