

# Ethics in statistics

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## Introduction

There are many different aspects of statistics. Statistics involves mathematics, computing, and applications to almost every field of endeavour. Each aspect provides an opportunity to spark someone's interest in the subject. In this paper we discuss some ethical aspects of statistics, and describe how an introduction to ethics has been incorporated into teaching elementary statistical methods at La Trobe University, Bendigo.

## Ethics in research

Human research is research that involves human beings or their data. A classic example of human research in health care is a drug trial where the efficacy of a new drug is tested on human beings before being made available more widely. In education, one might investigate the effectiveness of a new approach to presenting a mathematical idea in the classroom and compare it with a standard approach. In marketing research, one might wish to learn about the impact of a new advertising campaign through interviews with members of a focus group. All these are examples of human research, including even the simple survey where there is no experimentation involved. One could debate the meaning of the word 'research'—but this is not the place.

Data collection in human research has not always been conducted in an ethical manner. An infamous example is the study *Tuskegee Study of Untreated Syphilis in the Negro Male*. This was an investigation of how syphilis develops if it is not treated. It was conducted by the US Public Health Service from 1932 right up until 1972 when a story about the project was published in the media.

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Initially the project involved 600 impoverished and poorly educated African-American men, 399 of whom had syphilis and 201 of whom did not have the disease. The project consisted of tracking their health with respect to syphilis by conducting regular medical examinations over time. The participants were not informed of the real purpose of the study or given all the facts required to provide informed consent. Participants received free medical examinations, some meals and burial insurance. Even when penicillin was a standard treatment for syphilis in 1947, this was not offered to the men involved in the study. When the study was discontinued, only 47 of the original participants were still alive. Twenty-eight had died from syphilis and more than a hundred died from related complications. Forty wives had been infected and 19 children had been born with congenital syphilis. Survivors were granted financial compensation and an apology was issued by President Bill Clinton in 1997. This summary is based on [www.cdc.gov/tuskegee/timeline.htm](http://www.cdc.gov/tuskegee/timeline.htm) where more information can be found.

To ensure that human research is conducted in an ethical manner, researchers in Australia are guided by the *National Statement on Ethical Conduct in Human Research* (National Health and Medical Research Council, Australian Research Council, Australian Vice-Chancellors' Committee, 2013), which is often referred to simply as the *National Statement*. Every university and major hospital in Australia has a human research ethics committee that strives to ensure that human research is conducted in an ethical manner in the institution.

Since data collection and analysis are essential in many research projects, one way to introduce students to ethical issues in research is through a subject in statistics. In this paper we describe how this has been done at La Trobe University.

## Ethics in a statistics subject

Statistical Methods is a subject that serves as an introduction to statistics at La Trobe University, Bendigo; it is based on the text by Moore, Notz and Fligner (2013). Students from several different degree programs enrol in this subject, usually in their first year of study. It is compulsory within the psychology degree, and is taken as an elective by students in science and education. Since it is unlikely that students at this level will become involved in a major statistical project for some time, we wanted students to gain some knowledge about ethical issues that they will retain for many years. We decided that, in this context, one aim of Statistical Methods should be to acquaint the students with the *National Statement*.

One of the authors (TM) presents a guest lecture to introduce students generally to ethical issues in research, the role of Human Research Ethics

Committee, and ethical issues that arise in statistical analysis. Some of these issues are, on the surface, not obviously connected to ethics.

For example, deciding on the number of participants in a study, or sample size, has ethical implications. A sample size that is too small to detect the change being sought is a waste of time and money. A sample size that is larger than necessary is also wasteful. Often, sample sizes can be calculated by a mathematical formula: it's not a matter of guess work. This illustrates an ethical side of sample size calculations, which is a topic that is often met in a first course in statistics. See Altman (1980) for further discussion of ethical matters; Ryan (2013) is a recent book on sample size calculations.

However the main purpose of the guest lecture is to introduce students to the *National Statement*, and to set the scene for the exercises described below.

Students explore the *National Statement* through a series of exercises which are distributed to the class early in the semester. As well as introducing ethics, this format also engages students in independent learning at a basic level. The class is told that one examination question will be based on these exercises, and that it is their responsibility to read the *National Statement* and answer each of the questions in a short paragraph. In practice, the final exam question offers the students a choice of three of these exercises. The list below contains the preamble and questions framed as they are presented to the students, plus a few more.

## Exercises to explore the National Statement

The following exercises are designed to assist you to explore the *National Statement*. Often you are asked to give examples; try to make your examples realistic but hypothetical. It is simply a matter of thinking. Talking to colleagues may be useful. References to the relevant sections of the *National Statement* are given for each exercise.

1. Give one example of a research project that would be classified as 'human research', and another that would not be classified as 'human research'.
2. Name the four values on which the *National Statement* is based (Section 1). Explain the meaning of each value in 25 words or less.
3. The authors of the *National Statement* are three organisations, namely
  - (i) National Health and Medical Research Council,
  - (ii) Australian Research Council, and
  - (iii) Australian Vice-Chancellors' Committee.In less than 100 words, describe these organisations.
4. Give examples of research projects that you would describe as 'low risk' and 'high risk' (Section 2.1).

5. Give an example of where the benefit of the research may outweigh the risk to participants. Give another example where the benefit does not outweigh the risk (Section 2.1).
6. A person's participation in research requires their consent. List the conditions required to satisfy consent (Section 2.2).
7. Summarise the specific ethical considerations if researchers plan to 'bank' data for possible future use (Section 3.2).
8. Give the circumstances where it may be unethical for a researcher to continue a clinical trial. List the responsibilities of the researcher in this situation (Section 3.3).
9. Give an example of genetic research and the possible ethical implications for the family members of participants (Section 3.5).
10. Research involving certain categories of participants requires additional ethical consideration. Choosing one of these categories, state some of the specific issues that should be addressed when designing and conducting this type of research (Section 4).
11. Give examples where an existing relationship may unduly influence an individual's decision to participate in research and describe measures that can be taken to ensure consent is voluntary (Section 4.3).
12. In certain circumstances researchers are unable to obtain consent from potential participants. Identify the researcher's obligations in this situation (Section 4.4).
13. Explain the role of Human Research Ethics Committees (HRECs). Give reasons why HRECs are composed of the prescribed membership categories and why both institutional and non-institutional members are required (Section 5.1).
14. Describe the main responsibilities of institutions where research is conducted (Section 5.1).
15. Explain how potential or actual conflicts of interest could compromise research outcomes and the measures that can be adopted to manage this issue (Section 5.4).

## Conclusions

Our aim to acquaint the students with the *National Statement* is a modest objective that can be achieved with only a small impact on the syllabus. Indeed, perhaps, for some, it is a welcome relief to the numerical aspects of the subject. For most, it is a surprise that there are interesting non-numerical aspects to what is commonly perceived as a 'maths subject'.

In the last couple of years, the ethics component on the final examination has been a choice among questions 2, 6, and 13 in the list above. About 65% of students choose to answer question 2, with the remainder choosing equally

between the other two options. Perhaps most students perceived question 2 as more straightforward; this could be a matter for further investigation.

One might argue that this is not statistics. The counter argument is that statistics is important in research, and therefore associated ethical considerations are also important. So it is reasonable to start students thinking about ethical issues in a statistics subject.

## References

- Altman, D. (1980). Statistics and ethics in medical research III: How large a sample? *British Medical Journal*, 281(6251), 1336–1338.
- Moore, D. S., Notz, W. I. & Fligner, M. A. (2013). *The basic practice of statistics* (6th ed.). New York, NY: W. H. Freeman.
- National Health and Medical Research Council, Australian Research Council, Australian Vice-Chancellors' Committee. (2013). *National statement on ethical conduct in human research, 2007* (Updated March 2014). Retrieved from <http://www.nhmrc.gov.au/guidelines/publications/e72>
- Ryan, T. P. (2013). *Sample size determination and power*. Hoboken, NJ: John Wiley.