Research ethics and integrity basics

An introduction to the primary ethics and integrity issues in research

irecs

Funded by the European Union

Contents

The aims and learning outcomes 3

Aims 3

Learning outcomes 3

Introduction 4

Case study from Mexico 5

Case study from clinical research 7

Ethics review activity 8

Feedback on the ethics review activity 9

Research ethics issues in different disciplines 10

Nuclear physicist 10

Animal physiologist 10

Historian 10

Point to ponder 11

Research integrity 11

Types of research misconduct 12

Research with human participants 13

The need for informed consent 14

The need to minimise harms 15

The need to respect privacy 16

What is personal data? 17

End of module quiz 19

Glossary 21

Answers to the quizzes and activities 24

Research misconduct activity 24

Recipe for informed consent activity 24

End of module quiz 24

References and further resources 25

The aims and learning outcomes

Aims

The aim of this module is to provide learners from different backgrounds and disciplines with an overview of the primary ethics and integrity issues in research.

Learning outcomes

At the end of this module, learners will be able to:

1. Explain the importance of ethics and integrity in research.
2. Describe a range of ethics and integrity issues that can be associated with different types of research.
3. Summarise the primary ethics issues raised by research with human participants.

Introduction

Research can lead to great benefits.

We need look no further than the development of treatments and vaccines for combatting the coronavirus pandemic to understand the incredible potential for benefits.

But research does not always lead to benefits; it might also involve people, animals and resources in fruitless efforts and, at worse, it might cause great harm.

In this module, we consider some of the ethics and integrity issues that are associated with research across disciplines. We begin with an example case study from research that was undertaken during the coronavirus pandemic. When you read about the research, try also to think about what the associated ethics concerns might be.

Case study from Mexico

During the recent coronavirus pandemic, several research teams across the world explored the possibility of using drugs which were already used to treat other diseases.

One such drug, ivermectin, which is used to treat parasitic diseases, showed promising results in in vitro studies. Subsequent randomised controlled trials and systematic reviews seemed to indicate reduced hospital admissions and improvements in survival rates. However, further interrogation of the results revealed that over one third of 26 major trials of ivermectin contained serious errors. These included ethical transgressions and possible fraudulent manipulation of data.

In one study, the government of Mexico City provided residents who had tested positive for the coronavirus with nearly 200,000 ivermectin-based kits without telling them they were participating in an experiment.

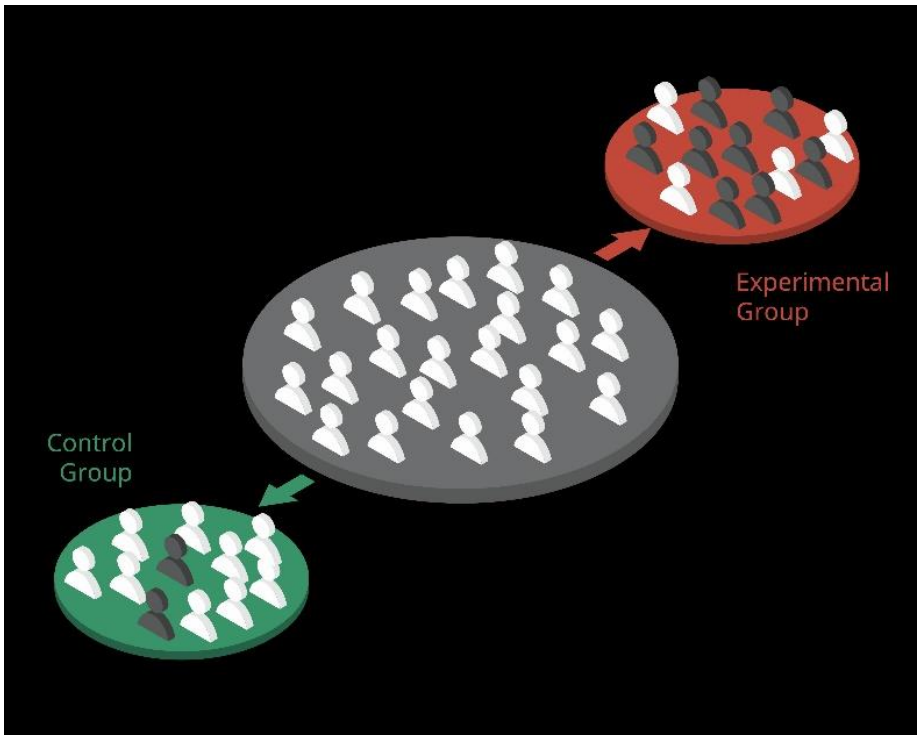
In another study in Arkansas, four prisoners with Covid were prescribed high doses of ivermectin. This was up to six times higher than the usual dose, but they were told that their treatment consisted of vitamins, antibiotics, and steroids. They suffered side-effects from the drug, and only found out six months later that they had been prescribed ivermectin. Articles about both studies were later retracted.

Here are some of the ethics issues we spotted:

- Participants were misled. Mexico City provided ivermectin kits but did not tell people that they were participating in an experiment.
- Participants took unknown risks. Prisoners in Arkansas were given doses of ivermectin that were 6 times higher than the usual dose.
- Participants were deliberately misinformed. Prisoners were told that they had been given vitamins, antibiotics and steroids and only found out 6 months later what they had really been given.
- Consent was not sought. Studies were published based on studies which were conducted without the informed consent of the participants.
- Errors or faults in clinical studies can lead to poorly evidenced or risky treatments. Over one third of 26 major trials of ivermectin contained serious errors.
- Results were unreliable:
    - Data was manipulated.
    - Studies were published based on faulty data.
- There were broad societal implications. The interest generated in ivermectin as a treatment for COVID-19 led to people taking it, sometimes in preference to evidence-based treatments and/or vaccinations.

Many of the ethics issues in research are obvious and there are clear guidelines about what how these ethics issues should be addressed. However, research can also generate ethics dilemmas that lead to debate about the best course of action. You will see this in the next example from clinical research.

Case study from clinical research



Clinical studies commonly include randomised control trials where the outcomes of two or more groups are compared to test the effects of particular interventions. Sometimes one of the groups is given a placebo (dummy pill) to act as the control, as in this study.

Stage 3 melanoma is an advanced form of skin cancer where the cancer has spread from the skin cells to the lymph vessels or lymph nodes. Treatment normally involves surgery, followed by radiotherapy and/or drug therapy to help prevent the cancer from returning.

Between 2008 and 2011, a new drug called ipilimumab, was tested in people post-surgery to see whether it had an impact upon the recurrence of melanoma and survival rates.

In total 951 patients were allocated at random to receive either the new drug or a placebo dummy pill over the three-year study period.

Results indicated that the new drug resulted in significantly higher rates of recurrence-free time and survival than placebo.

So, this was good news for people with melanomas. But are there any obvious ethics issues?

Ethics review activity

Read the following opinions and decide who you most agree with.

Sonia

This study provides very high-quality evidence for the efficacy of ipilimumab. The findings have the potential to benefit many patients. All the participants knew what was involved and consented to participate. Hence the study is ethical.

David

This study is unethical because the control group should not have been given placebo. Why wasn't the new drug compared with an existing treatment like interferon alpha? Those in the placebo group effectively went without treatment for three years.

Beth

There are times when, even though there is an existing treatment available, it is ethically permissible to test new treatments against a placebo because this gives a more realistic idea of the effect size and is more useful in the long run.

You can read the feedback below.

Feedback on the ethics review activity

Of the three options, Sonia is wrong; there are ethical concerns with this study. For the other two options, these could be debated. These types of dilemmas need to be scrutinised on a case-by-case basis. What does the Declaration of Helsinki say about this?

Placebos should only be used:

Where there are compelling and scientifically sound reasons why it is necessary to determine efficacy or safety and the patients who receive placebo will not be subject to additional risks of serious or irreversible harm.

But how do we know what counts as compelling and scientifically sound? And how do we know whether people who receive placebo are being put at risk?

As with many ethical guidelines, there can be disagreement about what they mean in practice. In this situation, when making decisions about the design of a study, it can help to remember the Golden Rule. Imagine yourself in the shoes of someone who is being invited to participate. What would you want to know and how would you want to be treated?

Research ethics issues in different disciplines

Some ethical issues are common across research disciplines. For instance, all researchers who work with human participants need to think about informed consent and privacy, regardless of their research discipline. Other ethical challenges are more specific to certain research fields. For instance, ethical challenges associated with research in artificial intelligence can be quite different to those involving animal experimentation or archaeology. Take a look at these three accounts from different disciplines.

Nuclear physicist

My research raises many safety concerns. I must ensure that experiments, particularly those involving high energy, radiation, or other hazardous materials, do not pose undue risk to researchers or to others, or to the environment. I also have to consider more long term, broader potential impacts of technological advances in my field. For instance, how can we balance the potential benefits of research for civilian applications like energy production, against the risks of its potential misuse for harmful purposes? Everyone knows that devastating harm that nuclear weapons can do.

Animal physiologist

My research involves experiments with animals like mice, rabbits, and pigs. The testing of new experimental medications in animals is necessary to ensure their safety before they are tested in humans. In the EU, there are strict regulations about animal experimentation in research based upon the '3 Rs' principles. The 3Rs stand for:

Replacement: Whenever possible, researchers should use non-animal methods or replace animals with high levels of sentience with animals that are less sentient.

Reduction: If animal use is unavoidable, researchers must use the minimum number of animals needed to achieve significant results.

Refinement: If animal use is unavoidable, researchers must refine experimental procedures to minimize pain, suffering, and distress, and enhance the welfare of the animals used.

Historian

As an historian, I face many ethical challenges when I'm conducting research. For instance, when I'm researching a sensitive topic, like war crimes during the second world war, is it always okay to name people if they are dead? Do the dead have rights to anonymity? How might their identification impact upon living relatives? Also, as this is a topic dear to my heart, should I try to minimise bias in my interpretation of events to make sure that I present a fair and accurate account? How am I supposed to do that?

Point to ponder

Do you know what the primary ethics issues associated with your type of research?

Research integrity

So far in this module, we have only referred to 'research ethics' but within this broad domain, a distinction is often drawn between matters of *research ethics* and matters of *research integrity*. Both are concerned with morality in research but matters of research integrity focus specifically upon the ethics issues that are associated with trustworthiness in research. Research integrity is needed to promote trust and confidence in all aspects of the research process. In the absence of research integrity, research misconduct can lead to the dissemination of unreliable information.

Types of research misconduct

There are many different types of research misconduct. Look at the following descriptions of misconduct and match the six different examples of types of research misconduct to their meanings.

Plagiarism	**Falsification**	**Conflicts of interest**
Fabrication	**Misrepresentation**	**Piracy**

1. The deliberate invention of data and/or other aspects of research (like ethics approval), presenting and sharing them as if they are real.

2. The failure to report matters that might prejudice the research conduct, findings and reporting such as financial interests or other personal gains.

3. The deliberate acquisition or exploitation of information from others without their authorisation.

4. The distortion of personnel facets like qualifications, experience or involvement or authorship.

5. The deliberate manipulation of data or research processes to arrive at certain results.

6. Using other people's writings, ideas or work without acknowledgement or permission.

You can check your answers on page 24.

Research with human participants

People can be involved in research in many different ways. For instance, they might be asked to take part in a survey, be interviewed, be observed, or participate in a clinical study. They might also be involved via use of their personal data or biological samples.

Here we touch upon three of the primary ethics requirements when research involves humans:

- The need for informed consent.
- The need to minimise harms.
- The need to respect privacy.

The need for informed consent

Informed consent is the cornerstone of ethical research with humans. It is of fundamental importance that people understand what a research project is about and provide their consent for taking part.

There are seven key ingredients for valid informed consent. Match the ingredients to their meanings. You can check your answers on page 24.

1. People must be mentally and physically capable of taking decisions for themselves.
2. There must be full disclosure about the purpose of the study, the methods, what participation will involve and how the results will be used.
3. People must be given a sufficient period to scrutinise the information and to ask questions.
4. Decision about whether or not to take part must be free from unfair enticements such as large sums of money or other disproportionate benefits.
5. Research participants must be free to leave the research at any time without providing an explanation or incurring any penalties.
6. Agreement to participate cannot be a one-off event. It must be open-ended throughout a research project and researchers may need to check this in a repeated manner.
7. Recording - The consent must be noted in some way. For instance, this may be written, or audio-recorded if consent is provided verbally.

All of these ingredients must be included for informed consent to be well-founded.

The need to minimise harms

Potential harms are not just associated with clinical studies. Other types of research can also lead to harm for participants. For instance, in-depth interviews might result in emotional distress and questionnaires might generate negative thoughts or feelings, especially if they address sensitive or personal issues; personal data breaches might violate confidentiality; and culturally insensitive conduct might cause great offence.

In many situations (especially in clinical research), it is not possible to design a study that is entirely without risk of harms, and it is also not always possible to predict harms in research accurately. Nevertheless, researchers must ensure that measures are in place to minimise risks of harms and that studies/participants are monitored for harm in an ongoing manner.

Research ethics is different from ethics in most other areas of professional activity in one very important respect.

When a professional and a client meet, it is usually on the basis of mutual interest.

For instance, in the health context, a patient goes to a doctor for help and the doctor gets paid for the service.

In research, the researcher is asking the participant for help. While researchers invariably benefit from research (employment, career, reputation etc.), it is rarely in the interests of participants to be involved in research.

The need to respect privacy

When we share personal information with certain professionals like doctors or solicitors, they are duty bound to keep this information confidential. Research often involves the same type of personal information, but researchers need to publish and share their findings. So, how do researchers safeguard participant privacy?

There are legal requirements for the processing of personal data (also referred to as personal information) to ensure the protection of privacy. All activities, including research, which involve personal data of any kind, in any way, must comply with data protection regulations. For researchers in Europe, this is the General Data Protection Regulation (GDPR).

From the moment personal data are gathered until the moment they are destroyed (commonly five-seven years after the study), the researcher has a responsibility to ensure that they safeguard the participants' rights to privacy and prevent breaches of data protection regulations.

What is personal data?

Do you know what is meant by personal data? Look at the following options and identify those that are personal data.

A name

A place of work

An address

An IP address

Genetic material

Religious opinion

Political opinion

Ethnicity

Feedback

All of the above qualify as personal information.

Personal data includes any information relating to a living individual who can be identified, directly or indirectly, from the data. This might include reference to an identifier such as a name, an identification number, location data, an online identifier or one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that person. This means that any information which might lead to identification of an individual, even if it does not include their name or other obvious identifiers, is considered personal data.

Additionally, certain types of personal data are deemed to be more sensitive than others. These include: genetic or biometric data, ethnic origin, religious beliefs, medical information, sexual preferences, records of legal proceedings and political opinions. Researchers are expected to take extra care when handling sensitive personal data.

Research ethics with humans presents one of the most difficult ethical challenges for a researcher. It might help to remember that research participants often provide a voluntary service to humanity and science without personal gain; they should be treated ethically in return.

End of module quiz

You can try these questions to see whether your learning from this module addresses the intended learning outcomes. When you have finished you can check the answers on page 24.

1. What is the *primary* reason for researchers to prioritise ethics and integrity considerations in the design and conduct of research?

A) To expedite the publication process and increase the likelihood of receiving grants.

B) To ensure compliance with institutional regulations and avoid potential legal repercussions.

C) To protect the wellbeing of participants and uphold the trustworthiness of research findings.

2. What are the seven key ingredients for valid informed consent?

A) Capacity, information, time, inducement, withdrawal, ongoing consent, recording.

B) Comfort, information, time, implementation, inducement, inclusion, ongoing consent, transcription.

C) Capacity, intensity, truth, induction, withdrawal, one-off consent, recording.

3. Which types of research studies are most likely to involve ethics and integrity issues?

A) Qualitative or mixed methods research studies, especially if involving children or vulnerable adults.

B) Quantitative research studies, especially regarding the demonstration of the validity, reliability and generalisability of the study during the dissemination of results.

C) All types of research studies require close attention to ethics and integrity issues throughout the design and conduct of the study.

4. How can researchers ensure that no harms come to participants in their studies?

A) By ensuring that all relevant integrity guidelines, regulations, and ethics codes are complied with, and that institutional ethics approval has been granted.

B) By identifying mistakes made in past studies conducted in similar circumstances and doing things differently.

C) In many situations, it is not possible to design a study that is entirely without risk of harms. Nevertheless, researchers must ensure that measures are in place to minimise risks of harms and that studies/participants are monitored for harm in an ongoing manner.

5. What ethical considerations are paramount in research involving human participants?

A) Maximising researchers' convenience and efficiency in data collection.

B) Safeguarding participants' rights, dignity, and wellbeing throughout the research process.

C) Minimising transparency to prevent dissemination of research outcomes before publication.

Glossary

Conflict of interest (CoI)

A conflict of interest arises when an individual has multiple interests or relationships that could potentially compromise their ability to act impartially, ethically, or in the best interest of others. This type of conflict typically occurs when personal, financial, professional, or other interests compete or conflict with the individual's duties, responsibilities, or obligations. For instance, when a researcher's affiliations with external organisations, such as membership of professional associations or advisory boards, create competing loyalties or obligations that could impact their decision-making within their primary role or organisation.

Fabrication

In research, fabrication refers to the creation of false information, such as data, qualifications or ethics approvals, with the intent to deceive or mislead others. It involves the manufacturing of something that is not true or the distorting of facts in order to portray a false reality.

Falsification

Falsification refers to the act of deliberately altering, manipulating, or misrepresenting data, evidence, or information with the intention of misleading others or distorting the truth. It involves presenting false or fabricated information as genuine or accurate, thereby creating a false impression or narrative.

General Data Protection Regulation

The General Data Protection Regulation (GDPR) is a comprehensive data protection and privacy regulation implemented by the European Union (EU). It came into effect on May 25, 2018, replacing the Data Protection Directive 95/46/EC. The GDPR aims to strengthen and harmonise data protection laws across EU member states, as well as to protect the privacy and personal data of individuals within the EU with key principles. For instance:

1. Consent: Individuals must provide clear and affirmative consent for the processing of their personal data.
2. Data Minimization: Organisations are required to collect and process only the personal data that is necessary for the specified purpose, and they must limit the retention of data to the minimum necessary timeframe.
3. Data Subject Rights: Individuals have enhanced rights over their personal data, including the right to access, rectify, erase, restrict processing, and portability of their data.

The GDPR applies not only to organisations based in the EU but also to any organisation that processes personal data of individuals within the EU, regardless of the organisation's location.

Golden Rule

The Golden Rule is a moral rule that is found in cultures and religious traditions around the world. In essence, it states that one should treat others as one would like others to treat oneself. The Golden Rule encourages empathy, compassion, and reciprocity in human interactions, emphasising the importance of considering the perspectives and wellbeing of others. Here are some of the formulations:

In Buddhism: "Hurt not others with that which pains yourself." (Udana-Varga 5.18)

In Christianity: "So whatever you wish that others would do to you, do also to them, for this is the Law and the Prophets." (Matthew 7:12, English Standard Version)
In Confucianism: "Never impose on others what you would not choose for yourself." (Analects 15.24)
In Judaism: "What is hateful to you, do not do to your fellow: this is the whole Torah; the rest is the explanation; go and learn." (Talmud, Shabbat 31a)
In Islam: "None of you [truly] believes until he wishes for his brother what he wishes for himself." (Hadith of the Prophet Muhammad, Sahih al-Bukhari and Sahih Muslim)

Informed consent
Informed consent refers to the voluntary agreement by an individual to participate in a particular activity, undergo a procedure, or receive a treatment after being provided with relevant information about the risks, benefits, alternatives, and implications involved. Informed consent is a fundamental ethical and legal principle in healthcare, research, and various other contexts where individuals may be asked to make decisions that might impact their wellbeing.
In research, informed consent is essential to protect the rights and welfare of research participants. Researchers are required to obtain informed consent from participants before involving them in a study, and participants have the right to withdraw their consent at any time without penalty.

Misrepresentation
Misrepresentation refers to the act of providing false, incomplete, or misleading information with the intention of deceiving or misleading others. It involves presenting something inaccurately or in a way that creates a false impression or understanding. For instance, making false or exaggerated claims about a product (like a drug) or service (like a treatment option) in advertisements or promotional materials.

Personal data
Personal data encompasses any information that relates to an identified or identifiable individual. It includes data that can directly identify a person, such as their name, address, email address, social security number, or phone number. It also encompasses data that, when combined with other information, could identify an individual, such as their date of birth, place of birth, gender, or biometric data.
In the context of data protection and privacy regulations, such as the General Data Protection Regulation (GDPR) in the European Union, personal data is subject to specific legal protections and requirements regarding its collection, use, disclosure, and security.

Piracy
Piracy in research refers to the unauthorised or unethical reproduction, distribution, or use of academic or scholarly work without proper attribution, permission, or acknowledgment of the original authors or copyright holders.

Plagiarism
Plagiarism is the act of presenting someone else's work, ideas, or creations as one's own without proper attribution or acknowledgment. It involves copying or closely paraphrasing the words, thoughts, or creative expressions of others and passing them off as original or independent work.

Randomised controlled trial

A randomised controlled trial (RCT) is a type of scientific study designed to evaluate the effectiveness of a particular intervention or treatment. In an RCT, participants are randomly assigned to one of two or more groups: the treatment group, which receives the intervention being tested, and one or more control groups, which may receive a placebo or standard treatment, or no treatment at all. RCTs are often described as 'blinded', which is implemented to minimise bias in the study. In single-blind trials, participants are unaware of their treatment assignment, while in double-blind trials, both participants and researchers are unaware of who is receiving the test intervention and who is receiving the control (standard treatment, placebo or no treatment).

Randomised controlled trials are broadly considered the gold standard for evaluating the efficacy and safety of medical treatments and interventions.

Systematic review

A systematic review is a comprehensive and rigorous method of summarising and synthesising existing evidence for a specific research question or topic. It involves systematically searching, selecting, appraising, and analysing relevant studies from the literature to provide a comprehensive overview of the available evidence.

Systematic reviews are broadly considered the highest level of evidence in evidence-based practice and are widely used to inform clinical practice, policymaking, and decision-making in various fields.

Answers to the quizzes and activities

Research misconduct activity

1. Fabrication
2. Conflicts of interest
3. Piracy
4. Misrepresentation
5. Falsification
6. Plagiarism

Recipe for informed consent activity

1. Capacity
2. Information
3. Time
4. Inducement
5. Withdrawal
6. Ongoing consent
7. Recording

End of module quiz

1.C

2. A

3. C

4. C

5. B

References and further resources

Websites

European Commission, Ethics for Researchers, available at: https://ec.europa.eu/research/participants/data/ref/fp7/89888/ethics-for-researchers_en.pdf

European Commission, The European Code of Conduct for Research Integrity, Available at: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/european-code-of-conduct-for-research-integrity_horizon_en.pdf

World Health Organization, Ensuring ethical standards and procedures for research with human beings. Available at: https://www.who.int/activities/ensuring-ethical-standards-and-procedures-for-research-with-human-beings

Journal

Research Ethics https://journals.sagepub.com/home/rea

Books

Bos, J. (2020). *Research ethics for students in the social sciences* (p. 287). Springer Nature.

Iphofen, R. (Ed.). (2020). *Handbook of research ethics and scientific integrity*. Cham: Springer.

London, A. J. (2021). *For the common good: Philosophical foundations of research ethics*. Oxford University Press.

Resnik, D. B. (2018). *The ethics of research with human subjects: Protecting people, advancing science, promoting trust* (Vol. 74). Springer.

Stewart Jr, C. N. (2023). *Research ethics for scientists: A companion for students*. John Wiley & Sons.

Temple, A. (2019). *The Postgraduate's Guide to Research Ethics*. Bloomsbury Publishing.

Wilson, H. F., & Darling, J. (Eds.). (2020). *Research ethics for human geography: A handbook for students*. Sage.

Woodfield, K. (Ed.). (2017). *The ethics of online research*. Emerald Publishing Limited.

Ivermectin

https://www.bmj.com/content/377/bmj.o917

https://www.bbc.co.uk/news/health-58170809

Ipilimumab

Eggermont, A.M., Chiarion-Sileni, V., Grob, J.J., Dummer, R., Wolchok, J.D., Schmidt, H., Hamid, O., Robert, C., Ascierto, P.A., Richards, J.M. and Lebbé, C., 2016. Prolonged survival in stage III melanoma with ipilimumab adjuvant therapy. *New England Journal of Medicine*, 375(19), pp.1845-1855.

Howick J (2018) Unethical World Medical Association standards for placebo trials? February 21, 2018. Forum, *Journal of Medical Ethics.* Available at : https://blogs.bmj.com/medical-ethics/2018/02/21/are-the-world-medical-associations-ethical-standards-for-placebos-ethical/