 Ethics in scientific research

This document supports the teaching of the Stage 6 Science Extension syllabus[[1]](#footnote-1).

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Preface

‘The right to search for truth implies also a duty; one must not conceal any part of what one has recognized to be true.’

Albert Einstein

Scientific freedom and scientific responsibility are essential to the advancement of human knowledge for the benefit of all. Scientific freedom is the freedom to engage in scientific inquiry, pursue and apply knowledge, and communicate openly. This freedom is inextricably linked to and exercised in accordance with scientific responsibility. Scientific responsibility is the duty to conduct and apply science with integrity, in the interest of humanity, in a spirit of stewardship for the environment, and with respect for human rights.[[2]](#footnote-2)

This document provides teachers with an introduction to ethics in scientific research, which is discussed in Module 1 of the science extension syllabus. Several ethical frameworks apply to different aspects of research, and this document introduces those frameworks. It also provides various exercises for teaching research ethics in the classroom. Science is not merely a collection of facts and concepts but is a systematic approach to inquiry. Just as history and philosophy are crucial elements of the scientific process, ethics is an essential aspect of the process of science. Ethics is a bridge that connects the scientific community with the lay society. Teaching ethics to high school students is not easy, as those students are only just beginning to develop their sense of values and ethics. Emotive responses, which often reflect students’ deepening understanding of values, typically do not lead to resolution of complex moral dilemmas. It is essential for classroom discussions on scientific ethics to be based on logical arguments, a reflection on values, and the perspectives and experiences of individuals throughout society.[[3]](#footnote-3) It is also important to realise that there are grey areas in ethical reasoning: rather than focus on right and wrong answers, classroom discussions on scientific ethics should emphasise logic and evidence.

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* Penny Gill, Science Curriculum Project Officer, Sydney

Contact

For more information, contact

Sham Nair  
Science Advisor, 7-12  
NSW Department of Education  
[sham.nair@det.nsw.edu.au](mailto:sham.nair@det.nsw.edu.au)

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Executive summary

Ethics is an integral part of conducting scientific research. Ethics, together with legal and moral considerations, place limits on scientific freedom. The scientific community accepts those limitations and generally operates within ethical boundaries. Indeed, scientists have been instrumental in developing the ethical standards that apply to research. The ethical standards ensure that scientific investigations and the knowledge gained through those investigations are aligned with the values held by the general society.

Ethical standards are based on several regulatory frameworks. Those frameworks are, in turn, based on universally accepted ethical principles. These include:

1. The principle of autonomy: making voluntary and informed decisions (i.e. capacity to act intentionally, with understanding, and without controlling influences)
2. The principle of nonmaleficence: No subject in a study is intentionally harmed or injured, either through acts of commission or omission
3. The principle of beneficence: Produce beneficial outcomes & positive steps are taken to prevent and to remove harm from the patient
4. The principle of justice: Equal access to care, benefits, compensation
5. The principle of confidentiality: maintaining anonymity and privacy.
6. The principle of non-deception: maintaining open and truthful communications

From these principles, separate ethical frameworks have been developed for research involving humans and vertebrate animals, the use of tissue- and bio-banks, and the sharing of research data. At institutions where such activities are conducted, regulatory bodies such as ethics committees oversee the implementation and maintenance of ethical standards. For example, investigators must obtain approval from ethics committees before undertaking research involving humans or vertebrate animals. Investigators must also ensure that all post-investigation activities, such as data sharing and publications, also comply with ethical standards. Failure to comply with ethical standards may attract reprimand, which may range from cautioning the researchers, to the rescinding of their research permits. In severe cases, legal action may be taken against the researchers.

By complying with ethical standards, researchers can ensure the integrity of their work. They can also be assured that their research and findings conform to the standards that are acceptable to the scientific community and the general society.

Ethical thinking in science

What is ethics?

Ethics is a set of moral obligations that define right and wrong in peoples’ behaviours, practices and decisions. While most principles of morality are personal (for example - truth-telling, avoidance of injury and harm), ethics refer to moral principles in whole societies. Many professional bodies (for example - medical, legal, engineering) have developed ethical standards that their members adopt. Those institutions may impose sanctions on members who violate those codes of ethics.

Ethics in science

‘The only ethical principle which has made science possible is that the truth shall be told all the time. If we do not penalise false statements made in error, we open up the way, don't you see, for false statements by intention. And of course a false statement of fact, made deliberately, is the most serious crime a scientist can commit.’

C. P. Snow, The Search, Charles Scribner's Sons, New York, revised edition, 1959

Scientific ethics calls for honesty and integrity in all stages of scientific practice[[4]](#footnote-4). This is a core principle of science. In science’s quest to understand nature, strict adherence to truth is a prerequisite to avoid being misguided. Many of the ethical principles of science relate to the production of unbiased scientific knowledge. As the growth of scientific understanding relies on extending existing knowledge, it is vital that the knowledge is generated through fair means. Scientific ethical principles guide all aspects of the scientific process, including the publication of data, peer review, experimental replication, research collaboration, validating research findings and confirming or raising questions about results. The peer-review process is an essential part of identifying and eliminating errors in science, as well as breaches to scientific ethics[[5]](#footnote-5).

Scientific advancement requires communities of people, such as researchers, students, lab technicians, the people who work in science publishing companies, employees at funding agencies, to interact with each other[[6]](#footnote-6). Such interactions generate ideas, communicate findings (for example - through journal articles and presentations at conferences) and train new scientists (in the scientific process). Importantly, those interactions also allow community members to verify information (peer review). Many leading research projects are enormous undertakings that involve many scientists: a 2015 paper on the discovery of the Higgs Boson[[7]](#footnote-7) holds the record for the highest number of authors in a single scientific paper – 5000!). Thus, scientific ethics provides ethical standards for collaboration, including data sharing, publications and intellectual properties.

Science is also accountable to the ethical standards of the broader society[[8]](#footnote-8). Most scientific research is publicly-funded, and societies may influence research priority areas for funding. For society to benefit from scientific research, as well as to be confident in the outcomes of scientific research, the scientific process must be transparent. It is also essential for the lay society to be confident that ethical standards are met in scientific research.

Science investigations are not ‘free-for-all’ endeavours. As in all areas of life, scientists are beholden laws of the countries and jurisdictions in which they live and work. Beyond those laws, scientists have constructed ethical guidelines so that the scientific work

* is of high quality;
* is performed in ethical ways (for example – declaring financial interests, identifying biosecurity threats, care of research animals, and ethical human experimentation);
* benefits society (for example - the types of research activities that are funded).

Other principles include[[9]](#footnote-9):

* Honestly reporting of scientific data;
* Carefully recording and analysing experimental results to avoid error;
* Openly sharing methods, data, and interpretations through publications and presentations;
* Validating results through replication and collaboration with peers;
* Properly crediting sources of information, data, and ideas;
* Fulfilling moral obligations to society in general, and, in some disciplines, responsibly weighing the rights of human and animal subjects.

Examples of ethically-questionable practices in scientific research

Science is morally neutral, while scientists are not[[10]](#footnote-10). Scientists are obliged to uphold the ethical principles that are a part of their profession. This section discusses ethically questionable practices in science. [Appendix 1](#Appendix1) contains more examples of such practices.

There are many debatable instances of ethically dubious practices in science. One familiar example of such practices occurred between the scientists who discovered the structure of DNA. Maurice Wilkins showed James Watson the X-ray crystallography image (photo 51). Although it was Rosalind Franklin (and not Maurice Wilkins) who obtained photo 51, she was not aware that Watson had seen it (Wilkins showed Watson the photo on a day when Franklin was not at work). There is little doubt that photo 51 allowed Watson and Crick to work out the structure of DNA. Watson, Crick and Wilkins received the 1962 Nobel Prize in Physiology or Medicine.

Another debate surrounds Robert Andrews Millikan’s paper on the charge on an electron[[11]](#footnote-11). Millikan had determined the charge of an electron in the famous oil drop experiment. His papers and notebooks reveal that he was selective in which measurements he selected for his calculations. Millikan states ‘It is to be remarked that this is not a selected group of drops but represents all of the drops experimented upon during 60 consecutive days’. However, Millikan's notebook shows that of 189 observations during the period in question, only 140 are presented in the paper. Some commentators suggest that this breaches ethical guidelines that relate to the collection, treatment and presentation of scientific data. However, modern scientists generally dismiss this assertion as other measurements have subsequently validated Millikan’s findings (his calculated value for the charge of the electron is one per cent lower than the currently accepted value, but the latter is six times greater than Millikan’s standard error!). Millikan received the 1923 Nobel Prize in physics.

The case of cold fusion shows another aspect of questionable scientific ethics[[12]](#footnote-12). Stanley Pons and Martin Fleischmann at the University of Utah concluded that they had found evidence of deuterium fusion occurring at room temperature (this was a ‘holy grail’ of energy research). Rather than publishing their findings in a peer-reviewed journal, they announced their findings at a press conference. However, other scientists could not replicate Pons and Fleischmann’s experiments. A few weeks later, the U.S. Department of Energy concluded that Pons and Fleischmann had not achieved cold fusion. Although their work was not considered to be scientific fraud, it was unethical as they did not follow the scientific process.

Here is a list of some examples of ethically-questionable practices in scientific research[[13]](#footnote-13):

* Publishing the same paper in two different journals without telling the editors.
* Not informing a collaborator of one’s intention to file a patent using data from a collaborative project
* Including a colleague as an author on a paper even though the colleague did not make a serious contribution to the paper
* Discussing with one’s colleagues confidential data from a manuscript that he/she is reviewing for a journal
* Using data, ideas, or methods (without permission) learned while reviewing grants or manuscripts
* Trimming outliers from a data set without discussing the reasons
* Using an inappropriate statistical technique to enhance the significance of the research
* Bypassing the peer review process and announcing the results of a study through a press conference
* Conducting a review of the literature that does not acknowledge the contributions of other people in the field or relevant prior work.

Journals often retract published articles if errors or misconduct is suspected. That this happens attests to the power of the self-correcting mechanisms in science. Figure 1 provides examples of article retractions.

Some examples pf retracted publications with reasons for retraction.

Figure 1[[14]](#footnote-14). Examples of published articles that were retracted because of significant errors or scientific misconduct on the part of the authors. Retraction is a severe action taken by journal editors. Low-level errors are often corrected with follow-up notifications in the journal, but articles are only retracted if the errors are considered to be of a severe nature (breach of scientific ethics).

Frameworks (principles) of bioethics

In many countries, bioethics frameworks are used to develop standards of professional scientific conduct. The following is a list of the core principles on which bioethics frameworks are based[[15]](#footnote-15):

1. The principle of autonomy: making voluntary and informed decisions (i.e. capacity to act intentionally, with understanding, and without controlling influences)
2. The principle of nonmaleficence: No subject in a study is intentionally harmed or injured, either through acts of commission or omission
3. The principle of beneficence: Produce beneficial outcomes & positive steps are taken to prevent and to remove harm from the patient
4. The principle of justice: Equal access to care, benefits, compensation
5. The principle of confidentiality: maintaining anonymity and privacy.
6. The principle of non-deception: maintaining open and truthful communications

Note that some organisations may specify a subset of these principles in their bioethics guidelines. However, in one form or another, bioethical frameworks are built on these principles.

Points to ponder

The following scenarios[[16]](#footnote-16) describe events at a research laboratory. For each scenario, consider if any ethical guidelines have been broken? Explain your answer.

Scenario 1: Incomplete data collection

The research protocol for a study of a drug on hypertension required the administration of the drug at different doses to 50 laboratory mice, with chemical and behavioural tests to determine the toxic effects of the drug. Tom had almost finished with the experiment for Dr Q. He had only five mice left to test. However, he wanted to finish his work in time to go on a holiday with his friends, who were leaving that night. He had injected the drug in all 50 mice but had not completed all the tests. He, therefore, decides to extrapolate from the 45 completed results to produce the five additional results.

Suggested answer: many different research ethics policies would hold that Tom has acted unethically by fabricating data. His actions would constitute a form of research misconduct, which is defined as "fabrication, falsification, or plagiarism" (or FFP). It is important to remember, however, that misconduct occurs when researchers intend to deceive: errors related to sloppiness, poor record keeping, miscalculations, bias, self-deception, and even negligence do not constitute misconduct. Also, reasonable disagreements about research methods, procedures, and interpretations do not constitute research misconduct.

Scenario 2: reporting errors

Dr T has just discovered a mathematical error in his paper that has been accepted for publication in a journal. The error does not affect the overall results of his research, but it is potentially misleading. The journal has just gone to press, so it is too late to revise the error before it appears in print. To avoid embarrassment, Dr T decides to ignore the error.

Suggested answer: Dr T's error is not misconduct nor is his decision to take no action to correct the error (the critical consideration is that the error does not affect the findings reported in his paper). Dr T should tell the journal (and any co-authors) about the mistake and consider publishing a correction or errata. Failing to publish a correction would be unethical because it would violate norms relating to honesty and objectivity in research.

Note: these two scenarios highlight the differences between questionable practice and misconduct.

Ethical frameworks for tissue banks

Tissue banks

Tissue banks are organisations that collect and store human tissues for medical research and development, treatment and education. The types of tissues collected can include corneas, skin, heart valves, musculoskeletal tissues and tumours. These tissues are accessible to medical staff and researchers, as well as companies that develop human therapeutics.

Guidelines for tissue banking[[17]](#footnote-17)

* Removal of tissues from volunteers
  + Donors must be informed about the intended uses of the tissues, as well as any risks to the donor from the removal process.
  + In NSW, some laws govern the removal of tissue from the dead – compliance with these laws is mandatory.
  + Tissue donors may be paid for their donation only to cover reasonable expenses but not as an inducement
* Acquisition and supply of tissue
  + Tissue banks may supply tissues on a cost recovery basis
  + Tissue banks should operate as non-profit professional organisations
  + The responsible government department should establish a central register of tissue banks approved for providing and tracking human tissue for medical treatment and research.
* Uses of tissues
  + Only tissues from accredited tissue banks should be used in the development of therapeutic products.
  + All research projects that use materials from tissue banks must obtain research ethics approval before undertaking the work.

Web resource

[Clark, G., Lipworth, W., Bokey, L., Little, M. and Kerridge, I., 2006. An empirical study of tissue banking in Australia: navigating regulatory and ethical challenges. Journal of Law and Medicine. 1:102-9 (this paper provides an overview of the regulatory landscape regarding tissue banks in Australia).](https://ses.library.usyd.edu.au/handle/2123/10800)

[Donor Tissue Bank of Victoria (it is an organisation that collects and supplies human tissues. It also provides stories of how those tissues have benefitted patients).](http://www.dtbv.org.au/)

Ethical frameworks for sharing and using research data

A key aspect of research activities is the production of data. In science, researchers share that information (data) as part of collaborative activities or the peer-review process (scientific publications). This aspect of research provides transparency and legitimacy to scientific knowledge construction. The availability of high-quality data, together with their attributes, is also essential for secondary research. However, there are circumstances wherein data sharing is not desirable or should be avoided (for example, personal health data). The primary funders of research grants in Australia (the National Health and Medical Research Council, and the Australian Research Council) are committed to openly sharing research data where possible. Researchers are encouraged to deposit their research data into a national data repository (the [Australian National Data Service](https://www.ands.org.au/))

Data sharing

The Australian Code for the Responsible Conduct of Research[[18]](#footnote-18) states: ‘Researchers have a responsibility to their colleagues and the wider community to disseminate a full account of their research as broadly as possible’. Both the ARC and NHMRC encourage the dissemination of all research outputs.

Data sharing is beneficial, as it:

* Encourages scientific enquiry and promotes innovation.
* Leads to new collaborations between data users and data creators.
* Maximises transparency and accountability.
* Reduces the cost of duplicating data collection.

The terms ‘data’ and ‘information’ are often used interchangeably, although usually ‘data’ refers to information in their raw form, whereas ‘information’ generally refers to data that have been interpreted, analysed or contextualised.

For data sharing purposes, data is often classified as low risk, medium risk or high risk based on the impact that the loss of confidentiality, integrity, or availability of the data would have on the individuals involved.

Research data that contains information that is confidential, of a national security interest, of commercial value or subject to ethical approval and oversight must be securely stored and shared only with appropriate permissions.

Ethics on the use of research data[[19]](#footnote-19)

The National Statement on ethical conduct in human research provides guidelines on the generation, collection, access, use, analysis, disclosure, storage, retention, disposal, sharing and re-use of data or information. They focus on ways that preserve privacy but enhance knowledge generation.

The ethics of data sharing centres on the following questions:

* What data or information are required to achieve the objectives of the project?
* How and by whom will the data or information be generated, collected and accessed?
* How and by whom will the data or information be used and analysed?
* Will the data or information be disclosed or shared and, if so, with whom?
* How will the data or information be stored and disposed of?
* What are the risks associated with the collection, use and management of data or information and how can they be minimised?
* What is the likelihood and severity of any harm/s that might result?

What can researchers and research administrators do?

Researchers and research institutions should consider the following measures:

* Institutions should encourage ethical data sharing
* Researchers should consider the need to share data when they design their projects.
* Collaborating researchers should agree on how data is stored, managed and destroyed. They also should agree on the ownership of any intellectual property created.
* Researchers should seek approval to share their data or to use data generated by others from their ethics committees (or other authorities). Even information in the public domain (including social media) may require specific permission for their use.
* Researchers and institutions should use techniques to support data sharing.
* Researchers should consider anonymising sensitive data that may then be shared. Researchers should reduce the risk of identification during the collection, analysis and storage of data and information.

Restrictions on data sharing

In some cases, scientific results cannot freely be shared. This applies to data that may be of commercial, national security or human health interest. Generally, the results of such research will not be published in publicly-accessible platforms. Alternatively, some journals may allow the findings to be published, without disclosing the data associated with those findings. For example, papers describing new drug discoveries rarely contain all the relevant information for readers to make independent assessments of the outcomes. These restrictions on data sharing may be detrimental to the scientific process.

Web resource

[Working with data](https://www.ands.org.au/working-with-data/sensitive-data/ethics-and-data-sharing)

Points to ponder

Read the following scenario[[20]](#footnote-20) about data sharing in scientific research and discuss any ethical issues that it raises (note that there are multiple viewpoints)

Dr Wexford is the principal investigator of a large, epidemiological study on the health of 10,000 agricultural workers. She has an impressive dataset that includes information on demographics, environmental exposures, diet, genetics, and various disease outcomes such as cancer, Parkinson’s disease (PD), and ALS. She has just published a paper on the relationship between pesticide exposure and PD in a prestigious journal. She is planning to publish many other papers from her dataset. She receives a request from another research team that wants access to her complete dataset. They are interested in examining the relationship between pesticide exposures and skin cancer. Dr Wexford was also planning to conduct a study on this topic. What is the ethically-appropriate course of action for Dr Wexford?

Suggested answer

Some issues to consider:

* Dr Wexford is ethically-obliged to share research data.
* Dr Wexford may be required to share her data under the rules of her research grant or the research institution where she is working.
* What happens if the other research group publishes papers with Dr Wexford’s data before she can do so.
* How will the request affect Dr Wexford’s intellectual property ownership of data?

Possible outcome: Dr Wexford could agree to share the data, albeit under certain conditions. Some conditions that may be imposed on the use of her data could include:

* Pre-defined uses of the data – the other research team states explicitly how Dr Wexford’s data will be used.
* Publication plans – the other research team indicates any plans they may have to communicate their work (which involves the use of Dr Wexford’s data), such as journal publications, conference proceedings and storing data in repositories.
* Authorship – the other research team agrees to include Dr Wexford and her team members in any publication arising from the use of her data.
* Collaboration – the other research team and Dr Wexford agree to collaborate on subsequent research involving her data formally.
* Intellectual property – this will require legal and binding agreements between the institutions involved. For example, the intellectual property arising from work conducted at Dr Wexford’s University may be owned by the institution. In such cases, intellectual property issues will be negotiated by Dr Wexford’s University and the other research team’s institution.

Human experimentation

Human experimentation is a category of research that involves the use of human subjects. Such research may include scientific and medical research but also extended to areas such as psychology, social science and education.

National Statement on ethical conduct in human research

The National Health and Medical Research, the Australian Research Council and Universities Australia released a national statement on the ethical basis of human research. All research must abide by these guidelines. The statement is the ‘ethos that should permeate the way those engaged in human research approach all that they do in their research’.

The statement focusses on minimising harm to the subjects of human experimentation. History is littered with examples of human research that has resulted in harm to the subjects involved (through technical error, ethical insensitivity, neglect or disregard or deliberate violations). Several principles governing human research have been produced since World War II, including the Nuremberg Code, the Helsinki Declaration and the Belmont Declaration. In Australia, the National Statement on ethical conduct in human research is guided by the following principles:

* Research merit and integrity
* Justice, including beneficence
* Non-maleficence
* Respect (for example -. in decision making or providing consent)

The Statement covers the following research elements:

* Element 1 – Research Scope, Aims, Themes, Questions and Methods
* Element 2 – Recruitment
* Element 3 – Consent
* Element 4 – Collection, Use and Management of Data and Information
* Element 5 – Communication of Research Findings or Results to Participants
* Element 6 – Dissemination of Research Outputs and Outcomes
* Element 7 – After the Project

Human Research Ethics Committees (HRECs)

At institutions that undertake human research, all research proposals must be approved by the HREC. The HRECs evaluate applications based on:

* How is the research question/theme identified or developed?
* How do the research methods align with the research aims?
* How will the researchers and the participants engage with one another?
* How will the research data or information be collected, stored, and used?
* How will the results or outcomes be communicated?
* What will happen to the data and information upon completion of the project?

Web resource

[An introduction to human experimentation](https://www.pcrm.org/research/healthcare-professionals/research-compendium/human-experimentation-an-introduction-to-the)

[Topics on human experiments](https://theconversation.com/us/topics/on-human-experiments-17611)

An example of human experimentation: The Tuskegee syphilis study[[21]](#footnote-21),[[22]](#footnote-22)

Scenario: In 1932, the Public Health Service (PHS) undertook a new study to examine the progression of untreated syphilis in African-Americans. Permission to use the medical facilities at the Tuskegee Institute was obtained, and human subjects were recruited from the Black community in the county by word-of-mouth. The recruited volunteers were told that they would be given free tests for ‘bad blood’, a term used locally to refer to a wide variety of ailments. This project became known as "The Tuskegee Study of Untreated Syphilis in the Negro Male," which would continue for forty years. The subject group was composed of 616 African-American men, 412 of whom had been diagnosed as having syphilis, and 204 uninfected people who acted as controls.

The participants were never told of the true nature of the study. A vital aspect of the study design was that the participants were never treated for syphilis, even though it was known since 1943 that penicillin was a safe, highly effective cure. Not only were the syphilitics among them not treated for the disease, but even those few who recognised their condition and attempted to seek help from PHS syphilis treatment clinics were prevented from doing so.

Eunice Rivers, an African-American PHS nurse, assigned to monitor the study, soon became a highly trusted authority figure within the subject community. She was primarily responsible for assuring the cooperation of the participants throughout the study. She was aware of the goals and requirements of the study, including the failure to fully inform the participants of their condition and to deny treatment for syphilis. It was her firm conviction that the men in the study were better off because they received superior medical care for ailments other than syphilis than the majority of African-Americans in Macon County.

The nature of the study was not withheld from the nation's medical community. Many venereal disease experts were contacted explicitly for advice and opinions. Most of them expressed support for the project. In 1965, 33 years after the Study's initiation, Dr Irwin Schatz became the first medical professional to object to the Study on moral grounds. The PHS ignored his complaint. The following year, Peter Buxtin, a venereal disease investigator for the PHS, questioned the morality of the Study. A panel of prominent physicians was convened by the PHS in 1969 to review the Tuskegee study. The panel did not include African-Americans or medical ethicists. Ignoring the fact that it violated the human experimentation guidelines adopted by the PHS in 1966, the panel's recommendation that the Study continue without significant modification was accepted.

By 1972, Buxtin had resigned from the PHS and entered law school. Still bothered by the failure of the agency to take his objections seriously, he contacted the Associated Press, which assigned reporter Jean Heller to the story. On July 25, 1972, the results of her journalist investigation of the Tuskegee Study of Untreated Syphilis in the Negro Male were published. The response to Heller's revelations was broad-based public outrage, which finally brought the Study to an immediate end.

By the end of the study, 28 persons had died from the disease, 100 persons had died from related disorders, and 40 wives and 19 children had been infected with syphilis.

Ethical considerations: There are seven main points which are regarded as highly unethical in the study:

* The patients did not consent to be a part of the study.
* The participants were not informed of all of the known dangers.
* The participants had to agree to an autopsy after their death to have their funeral costs covered.
* Scientists denied treatment to patients to observe the fatal progression of the disease.
* Participants were not given the cure, even when it was widely known and readily available.
* The designers used a misleading advertisement to recruit participants, using the slogan; ‘Last Chance for Special Free Treatment’. The subjects were not treated but instead were recruited for a risky medical procedure (spinal tap).
* At the beginning of the study, the subjects were not informed about the whole purpose of the research. The experiment was, at the time, seen as potentially beneficial for the humankind but did not consider the harm caused to individuals and their families

The ethics of using animals in research

Animal models in research have historically played a pivotal role in advancing the scientific understanding of the living world. Humans have benefited from animal-based research. Generally, research involving human experimentation is conducted first with animals and then, if it is deemed to be safe, with human volunteers. For example, animals are used in research on human diseases, studies related to addiction and drug abuse and on the effects of space travel. Despite many years of animal-based experimentation, the use of animals in research continues to be a topic of public and scientific debate.

The scientific rationale for using animals in research

Worldwide, several national committees have examined the use of animals in research. There are substantial grounds for justifying animal research, particularly those that are focused on benefitting humans. For example, the Nuffield Council on Bioethics concluded that ‘because of evolutionary continuities in the form of behavioural, anatomical, physiological, neurological, biochemical and pharmacological similarities between animals and humans there are sufficient grounds for the scientific hypothesis that, in specific cases, animals can be useful models to study particular aspects of biological processes in humans, and to examine the effects of therapeutic and other interventions’[[23]](#footnote-23).

Three main types of research that involve the use of animals include:

* Research that advances scientific knowledge (for example - understanding genetic, physiological and biochemical mechanisms).
* Research that uses animals as models to study the mechanisms of human disease and to develop interventions.
* Research that uses animals in toxicity testing.

Ethical considerations

The biological similarities between humans and animals used in research imply that those animals may possess certain traits (for example - sentience, higher cognitive capacities, the capacity to flourish, sociability and possession of life) that make their use morally troubling. The mistreatment of animals in the name of scientific research is another area of concern. In many countries, the use of animals in research is regulated by laws and statutes. From the 18th century onwards, several countries enacted laws to protect animals, such as the 1876 Cruelty to Animals Act in England. In Australia, animal welfare legislation is enacted and regulated by its states and territories. In NSW, the ethics guidelines concerning the use of animals in research are derived from the Animal Research Act 1985 and the Animal Research Regulations 2010.

Animal ethics committees

Animal ethics committees at research institutions are responsible for administering regulations relating to the ethics and morality of using animals in research, including the necessity of such research and the right to ‘use’ animals for the benefit of humanity. Animal ethics committees review every research proposal that uses vertebrates, whether they be for research or educational purposes. Some of the questions that guide their review are:

* What are the goals of the research?
* What is the probability of success?
* Which animals are to be used?
* What effect will there be on the animals used in the experiment?
* Are there any alternatives to using animals in research?

In Australia, the National Health and Medical Research Council (NHMRC) has produced guidelines[[24]](#footnote-24) that researchers must adhere to. Institutional animal ethics committees evaluate research proposals using these guidelines. The following list summarises the main guidelines for animal research in Australia:

* Respect for animals must underpin all decisions and actions involving the care and use of animals for scientific purposes. This respect is demonstrated by:
  + Using animals only when it is justified.
  + Supporting the wellbeing of the animals involved.
  + Avoiding or minimising harm, including pain and distress, to those animals (what is likely to happen to the animals during the project, including adverse effects from husbandry, supply, transport and procedures).
  + Applying high standards of scientific integrity.
  + Applying replacement, reduction and refinement (the 3Rs) at all stages of animal care and use:
    - The Replacement of animals with other methods (for example - cell cultures, tissue banks, abattoir materials).
    - The Reduction in the number of animals used.
    - The Refinement of techniques used to minimise the adverse impact on animals.
* Knowing and accepting one’s responsibilities (adherence to these principles are monitored and implemented by the relevant institutional Ethics Committees).

Example of animal use in research: The Zebrafish model of Duchene’s Muscular Dystrophy[[25]](#footnote-25)

The following discussion is an example of a research project that involves the use of animals. In this project, Dr Don Love and his research team at Auckland University are using zebrafish as a tool to study heritable human diseases such as Duchene’s Muscular Dystrophy (DMD). The mutated zebrafish (sapje mutants) are genetically modified to express the DMD condition.

Why zebrafish?

Zebrafish, Danio rerio, is native to the slow, warm fresh waters of the Ganges River. They are easy to maintain and propagate in the laboratory. They are inexpensive, and much of the embryonic development is visible with light microscopy.

Zebrafish are an example of a model organism. Model organisms are non-human species used by scientists to understand the biological processes behind many systems in humans. Model organisms exhibit genetic, molecular, biochemical or physiological similarities to humans. By using model organisms such as Zebrafish, scientists can understand many essential aspects of human conditions before working on humans (e.g. developing treatments).

What is muscular dystrophy?

Duchenne Muscular Dystrophy (DMD) is a neuromuscular disease. It results in progressive muscle degeneration and weakness. Initially, it affects the voluntary muscles, causing weakness and dysfunction. Later, involuntary muscles degenerate (for example the diaphragm and the digestive system), resulting in the death of the affected individuals. Currently, there is no cure for DMD.

DMD is caused by a defect in the gene coding for dystrophin protein (expressed in muscle cells). In humans, the dystrophin gene is found on the X chromosome and is recessive. This means that the disease is sex-linked and primarily affects boys. Females with one copy of the mutated dystrophin gene are carriers and do not express the condition. Females with two copies of the mutated gene will develop DMD. DMD affects approximately 1 in 3,000 live male births.

Giving a fish muscular dystrophy

Since it is not possible to experiment on humans, scientists use the Zebrafish model of the disease to understand the condition better. Normal Zebrafish possess the dystrophin gene (which is very similar to the dystrophin gene in humans). To create Zebrafish models, scientists use a genetic technology called RNA interference. As a result of this genetic manipulation, those Zebrafish cannot express the dystrophin gene and thus develop DMD. Fish with the disease are easily identified because they cannot swim normally.

The ethics of the zebrafish research

Since the zebrafish is a vertebrate animal, the research project must be approved by an animal ethics committee before it can be carried out. Before approving the research, the ethics committee must be convinced that the value of the outcomes of the research must be greater than the suffering imposed on the animals. Furthermore, the researchers must demonstrate that they will take all measures to minimise any unavoidable suffering. This is estimated against a standardised scale of degrees of suffering. During the research, the wellbeing of the fish is carefully monitored and dealt with humanely. In this case (the DMD research using Zebrafish), the animal ethics committee at the University of Auckland approved the study because of the ultimate potential of the work to lead to treatments for DMD.

Web resource

* [Watch videos of high school students discussing the ethics of the zebrafish DMD project](https://www.sciencelearn.org.nz/resources/2112-dr-love-s-zebrafish)
* [Experimenting on animals](http://www.bbc.co.uk/ethics/animals/using/experiments_1.shtml) (A discussion on the ethics of using animals in experimentation)
* Foëx B. A. (2007). The ethics of animal experimentation. Emergency medicine journal: Emergency Medicine Journal, 24(11), 750-1. (A historical and philosophical look at animal ethics).

Activity: evaluating animal ethics

You are a member of the Institutional Animal Ethics Committee. You have been asked to evaluate two research proposals, shown in Table 1, that involve the use of animals. After studying the information, indicate the potential benefits of the projects in Table 2. After that, indicate if you think that the projects should be approved or not. Provide your reasons, especially the ethical issues raised by the research[[26]](#footnote-26).

Research proposal 1: prostate cancer

A research group at your University has developed a possible treatment for prostate cancer. The group proposes to investigate the potential benefits of using nanotechnology to deliver an anti-cancer drug to prostate cancer tissues. To determine its efficacy, the researchers will carry out the investigation using mice.

The experimental design uses four groups of mice that have been genetically engineered to develop prostate cancer. Group 1 has 25 mice that will be injected with a predefined dose of the therapeutic drug that is coupled to nanoparticles. Group 2 has 25 mice that will receive the same dose of the drug, but without the nanoparticles. Group 3 contains 25 mice that receive the nanoparticles, but no drugs. Group 4 includes 25 mice that will not receive any treatment (no therapeutic drug or nanoparticles but will be injected with normal saline solution). Throughout the experiment, the mice will receive water and food, as described in animal maintenance protocols. They will also be monitored for signs of disease or distress (such mice will be humanely euthanised). One week after receiving the treatments, all mice will be sacrificed by carbon dioxide asphyxiation and their prostate tissues examined for progression of the disease.

Analysis

|  |  |
| --- | --- |
| Risk and benefits | Comments |
| Benefits for humans  (how will humans benefit from this research?) |  |
| Benefits for animals  (how will animals benefit from this research?) |  |
| Risks for humans  (what are the risks to humans from this research) |  |
| Risks for animals  (what are the risks to humans from this research) |  |

Conclusion (Is the project approved? Using scientific and ethical reasoning, justify your decision)

Research proposal 2: party drugs[[27]](#footnote-27)

A research group at your University wants to determine the use of the drug ecstasy (methamphetamine) in parties. They propose to use rats, which will be maintained in a high-temperature enclosure (that mimics the high-temperature environments of party rooms). The rats can consume ecstasy solutions by pressing down on a lever in their cages. The rats will also be surgically-implanted with a catheter that allows the researchers to determine the quantity and frequency of ecstasy consumption. The experimental group consists of rats that will be maintained at 30oC, while the control group contains an identical number of rats which will be maintained at 23oC. All animals will be provided with food and water according to standard protocols. They will also be observed for distress (for example, hyperthermia – in which case, they will be humanely sacrificed). At the end of the experiment, all animals will be euthanised using standard procedures.

Analysis

|  |  |
| --- | --- |
| Risk and benefits | Comments |
| Benefits for humans  (how will humans benefit from this research?) |  |
| Benefits for animals  (how will animals benefit from this research?) |  |
| Risks for humans  (what are the risks to humans from this research) |  |
| Risks for animals  (what are the risks to humans from this research) |  |

Conclusion (Is the project approved? Using scientific and ethical reasoning, justify your decision)

Teaching research ethics

Research ethics may be taught through exercises that require students to analyse experimental information and evaluate the ethical consequences of the research. For the Science Extension Research project, ask students to consider the ethical implications of the research by answering the following questions[[28]](#footnote-28) (the ethical criteria are shown in brackets):

* Has everybody who is taking part in your research freely agreed to take part with a good understanding of the risks of the research and their role in it? (Respect; informed consent).
* Have you completed a health and safety check, and risk assessment? (Safety)
* What impact could your research have on your participants, the environment, or the wider community? If you think your research could do harm, is it justified, and should you continue? Have you done everything you can to reduce or remove the risk? Are the harms and benefits of your research shared fairly between the participants? (Harm vs. Benefit)
* How will you choose your participants? (Bias; random sampling)

Classroom discussions

The following activities have been adapted from [Ethical research – activities and case studies](https://bigpictureeducation.com/ethical-research-activities-and-case-studies).

* Ask students to list the consequences of lying (generic). Later ask students to consider the consequences of scientific dishonesty. Note to teachers: let his be an open-ended activity but ask students to provide reasoned arguments.
* Case studies:
  + Case study 1: Alcohol and behaviour

Ethan was interested in the ways alcohol and other substances affect mood and behaviour, and how this behaviour might also be influenced by factors such as peer pressure, social context and legislation. His EPQ research question was: ‘Is legislation the most effective way to control alcohol-related antisocial behaviour?’ Ethan used textbooks and websites to find out how alcohol is processed in the human body and how it affects the body and brain. He also researched relevant legislation in the UK and other countries, both now and in the past. He then thought it would be interesting to carry out some of his own observations and gather primary data. At a party where students from his college were drinking alcohol, he decided to record video clips on his phone and see how people’s behaviour changed during the evening. He did this without telling people at the party what he was doing, as he did not want them to alter their behaviour.

* + Case study 2: Genetic disease

Mindi’s EPQ research question was: ‘What is the best way to control genetic diseases?’ A lot of her work involved using textbooks and the internet to find out about a range of genetic diseases and the ways that embryos produced by IVF can be screened before being implanted in the mother. She also researched genetic counselling. Mindi learned that some genetic diseases were more common in certain ethnic groups and decided to gather her own data on this. Mindi produced a questionnaire that asked people about their ethnic origins, their family relationships, and whether there was any family history of genetic disease. She gave her questionnaire to students at her school and asked them to complete it in consultation with family members. Several students and their families found the questionnaire intrusive and upsetting. Some people became quite angry and complained to the school.

Both Ethan and Mindi committed ethical breaches in their research. Using the relevant ethical frameworks, explain the ethical rules that were broken and how Ethan and Mindi could have conducted their research ethically.

Resources for further exploration of ethics

* [Scientific ethics quiz](https://www.visionlearning.com/en/library/Process-of-Science/49/Scientific-Ethics/161/quiz), (a resource for classroom use)
* [Ethics quiz, (a resource for classroom use)](http://about.elsevier.com/ethicsquiz/quiz.asp)
* [Online ethics](http://www.onlineethics.org/) (this website contains multiple resources for classroom instruction in ethics).
* [Children and health research](http://nuffieldbioethics.org/project/teaching-resources/ethics-clinical-research) (teaching resources on ethical issues in clinical medicine)
* [Forensic use of bioinformation](http://nuffieldbioethics.org/project/teaching-resources/forensic-bioinformation) (teaching resource)
* [Research involving animals](http://nuffieldbioethics.org/project/teaching-resources/13937-2) (teaching resource)

References

[Ethical Codes & Research Standards Ethical Codes](https://www.hhs.gov/ohrp/international/ethical-codes-and-research-standards/index.html) by the U.S. Department of Health & Human Services

[The Belmont Report](https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html), by the U.S. Department of Health & Human Services

[Engineering ethics](https://www.raeng.org.uk/policy/engineering-ethics/ethics#statement), by the Royal College of Engineers

[Events that Brought Research Ethics to Public Attention](https://www.brynmawr.edu/ethics-fieldwork/events-and-responses); Bryn Mawr College, USA.

[Informed Consent Template](https://www.who.int/rpc/research_ethics/informed_consent/en/), by the World Health Organisation

“All this knowledge, all our knowledge, has been built up communally; there would be no astrophysics, there would be no history, there would not even be language, if man were a solitary animal. What follows? It follows that we must be able to rely on other people; we must be able to trust their word. That is, it follows that there is a principle which binds society together, because without it the individual would be helpless to tell the truth from the false. This principle is truthfulness.”

Jacob Bronowski, quoted by Bentley Glass[[29]](#footnote-29)

Appendix 1: some historical examples of unethical practices in science

The following table summarises examples of unethical practices in scientific research. They span practices such as publishing false data, violation of bioethics laws, misuse of scientific information and the vested interests that influence the outcomes of research investigations. The following general references contain more examples of unethical scientific practices:

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2. On being a scientist. Committee on the Conduct of Science, National Academy of Sciences of the United States of America. (1989). *Proceedings of the National Academy of Sciences of the United States of America*, 86(23), 9053-74.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Researcher | Discovery | Unethical conduct | Consequence | Reference |
| Jan Hendrik Schön, Bell Laboratories | Carbon-based materials that possessed properties such as superconductivity | Schon was a physicist who was working at the prestigious Bell Laboratories. He published articles in leading scientific journals about his discovery or invention of new materials that possessed sought-after features, such as electrical conductivity. However, other scientists could not replicate Schon’s findings, and an investigation at Bell Laboratories soon established that he had fabricated the data in 16 out of the 25 papers he published. | His employer, Bell Laboratories dismissed him | Service RF. Bell Labs. Winning streak brought awe, and then doubt. *Science*. 2002. 297:34.  <https://en.wikipedia.org/wiki/Sch%C3%B6n_scandal> |
| Hwang Woo-Suk of the Seoul National University | Cloning of human embryos | Hwang was a stem cell biologist who, in manuscripts published in leading scientific journals, claimed to have isolated stem cells from cloned human embryos. An investigation by Seoul National University established that his experimental data were fabricated. Furthermore, it was alleged that he had bought biological materials (e.g. human eggs) from people working in his laboratory (a violation of bioethics laws). | Hwang was sentenced to 2 years imprisonment for breaching South Korea’s bioethics laws. | Cyranoski, David. “Woo Suk Hwang Convicted, but Not of Fraud.” Nature News, Nature Publishing Group, 26 Oct. 2009, [www.nature.com/news/2009/091026/full/4611181a.html](http://www.nature.com/news/2009/091026/full/4611181a.html)  <https://en.wikipedia.org/wiki/Hwang_Woo-suk> |
| Luk Van Parijs, Massachusetts Institute of Technology | Immunology & RNA interference | Van Parijs was a leading scientist in the field of autoimmunity and the role of RNA interference in autoimmunity. An investigation by the Massachusetts Institute of Technology (MIT) identified that he had published manuscripts with fabricated data. He had also obtained federal research grants using those fraudulent data. He was dismissed from the University and prosecuted. | Van Parijs received six months house arrest sentence for grant fraud. | Reich, E., (2011). Fraud case we might have seen coming. Retrieved from <https://www.nature.com/news/2011/110728/full/news.2011.437.html>  <https://en.wikipedia.org/wiki/Luk_Van_Parijs> |
| U.S. military | Agent Orange | In his graduate research, Arthur Galston discovered a type of chemical (called a defoliant) that destroys the leaves of plants. This finding was used by the American military to develop Agent Orange, which was used to destroy forests in Vietnam during the Vietnam War. However, Agent Orange also causes numerous medical complications and many Vietnamese were affected by the chemical. Although Galston was not involved in the development of Agent Orange, he felt ethically obliged to highlight to the American government the problems associated with the use of Agent Orange, and that the use of this substance constitutes chemical warfare (to which America was opposed). | After much debate, and through the activism of Arthur Galston, the use of Agent Orange was banned. | Galston AW. Science and social responsibility: A case history. *Annals of the New York Academy of sciences.* 1972;196(4):223-35.  <https://en.wikipedia.org/wiki/Arthur_Galston>  <https://en.wikipedia.org/wiki/Agent_Orange> |
| The tobacco industry | Tobacco smoke | The Environmental Protection Agency in 1993 stated that ‘environmental tobacco smoke’ should be classified as a class A carcinogen. In response to this shift in the regulatory environment, the tobacco industry created a non-profit organisation, the Centre for Indoor Air Research, to fund well over 200 published studies to counter the EPA finding. Additional steps included (1) formation of a consultant program funded by U.S., Japanese, and European tobacco companies to present favourable findings at scientific meetings and to publish findings; (2) introduction of bias into studies by misclassification of study subjects to reduce the apparent impact of second-hand smoke; and (3) placement of industry in-house scientists on journal editorial boards. | Declarations of funding sources are now mandatory in scientific publications. These may indicate conflicts of interest when interpreting the significance of the published research. | Muggli, Monique E, Jean L. Forster, Richard D. Hurt, and James L. Repace. The Smoke You Don’t See: Uncovering Tobacco Industry Scientific Strategies Aimed against Environmental Tobacco Smoke Policies. *American Journal of Public Health*. 2001. 91(9):1419-1423.  Tong, Elisa K. and Stanton A. Glantz. “Tobacco Industry Efforts Undermining Evidence Linking Secondhand Smoke with Cardiovascular Disease.” *Circulation*. 2007. 116:1845-1854. |

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2. [AAAS Statement on Scientific Freedom and Responsibility](https://www.aaas.org/page/aaas-statement-scientific-freedom-and-responsibility) [↑](#footnote-ref-2)
3. [This Is Your Brain: Teaching About Neuroscience and Addiction Research](https://common.nsta.org/resource/?id=10.2505/9781933531229) [↑](#footnote-ref-3)
4. [Scientific culture](https://undsci.berkeley.edu/article/0_0_0/socialsideofscience_05) [↑](#footnote-ref-4)
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18. [Code for Responsible Conduct of Research](https://nhmrc.gov.au/sites/default/files/documents/attachments/grant%20documents/The-australian-code-for-the-responsible-conduct-of-research-2018.pdf) [↑](#footnote-ref-18)
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21. [Case](https://www.onlineethics.org/Resources/precollege/scienceclass/sectone/chapt4/cs3.aspx) Online Ethics Center for Engineering 7/20/2006 OEC [↑](#footnote-ref-21)
22. [Tuskagee syphilis study](https://explorable.com/tuskegee-syphilis-study) [↑](#footnote-ref-22)
23. [The ethics of research involving animals](http://nuffieldbioethics.org/wp-content/uploads/The-ethics-of-research-involving-animals-full-report.pdf) [↑](#footnote-ref-23)
24. [Australian code for the care and use of animals in research](https://nhmrc.gov.au/about-us/publications/australian-code-care-and-use-animals-scientific-purposes#governing_principles) [↑](#footnote-ref-24)
25. Adapted from [Zebrafish make a difference](https://www.sciencelearn.org.nz/resources/2515-zebrafish-make-a-difference) & [Zebrafish](https://www.sciencelearn.org.nz/resources/2112-dr-love-s-zebrafish) [↑](#footnote-ref-25)
26. This activity was adapted from [This Is Your Brain: Teaching About Neuroscience and Addiction Research](https://common.nsta.org/resource/?id=10.2505/9781933531229) [↑](#footnote-ref-26)
27. Adapted from Cornish, JL, Clemens, KJ. Thompson, MR, Callaghan, PD, Dawson, B & McGregor, IS, High ambient temperature increases intravenous methamphetamine self-administration on fixed and progressive ratio schedules in rats J Psychopharmacol (2008) 22(1) 100-110 [↑](#footnote-ref-27)
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