Why Is Scientific Research Regulated?

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AMGEN Biotech Experience

Scientific Discovery for the Classroom

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Program

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Scientific Discovery for the Classroom

Australia

Why Is Scientific Research Regulated?

Stage 6 | Science | 2022



Unit overview

Context and Unit Description

This unit of work allows students to investigate the need for regulation of scientific research, and the ethical issues that surround current scientific research. The investigation of the ethical issues, students will include a range of international and domestic codes of conduct within scientific research and practice.

Students will evaluate areas such as:

- · Genetic modification of sex cells and embryos
- Testing and research of pharmaceuticals
- Products and processes of the nuclear industry, and uses of radiation
- Protection of Indigenous cultural and intellectual property, with reference to bioprospecting and mining

Students will use a different example from the list above to:

- 1. Evaluate the need for the regulation of scientific research
- Evaluate the need for the regulation of scientific research
 Assess ethical issues surrounding current scientific research
- 3. Assess a range of international scientific codes of conduct in regard to scientific research and practice
- 4. Evaluate the effectiveness of international regulation in scientific research and practice

Assessment overview

AFL (PRE): Assessment for learning involves teachers using evidence about students' knowledge, understanding and skills to inform their teaching.

Task: Class quizzes; secondary sources research task; practical work (group and individual); first hand investigations,

AOL: provides evidence of student learning at particular key points in time.

Task: Student Research Project -Open Ended

AAL: Assessment as learning occurs when students are their own assessors.

Task: informal quizzes; worksheets on taught content; analysis of practical results, data and trend

Glossary term	Definition
Act	
Law	
Regulation	

Teaching, learning and assessment (with resources embedded)

Topic:

Inquiry question: Why is scientific research regulated?

	Stage 6			
Knowledge and Understanding:	anding: INS 12-14 - evaluates the implications of ethical, social, economic and political influences on science.			
Working Scientifically:	INS 11/12 - 5 analyses and evaluates primary and secondary data and information. INS 11/12 - 7 communicates scientific understanding using suitable language and terminology for a specific audience or purpose.			
Additional Content:	Additional Content:			
Learning Intention:	I am learning why scientific research is regulated So that I can Investigate the need for regulation of scientific research. Investigate and assess ethical issues surrounding current scientific research Investigate a range on intentional codes of conduct in regards to scientific research and practice Evaluate the effectiveness of international regulation in scientific research and practice.			
Success Criteria:	Explain the need for regulation of scientific regulation Explain and assess the ethical issues surrounding scientific research Compare and contrast a range of international scientific codes of conduct in regards to scientific research Evaluate the effectiveness of international regulation in scientific research and practice			

Teacher Engage:

Students...

Band 1-2	Band 3-4	Band 5-6
As students to describe what biotechnology means to them. Students are to research the meaning of biotechnology and create a definition with assistance from the teacher.	AFL: Teacher initiates a conversation with students about biotechnology. What is biotechnology? What biotechnology do you know about? How does biotechnology affect you every day? Is biotechnology a positive or negative thing? Why is it important for biotechnology to be regulated? (10 minutes in total) Biotechnology	

Students Explore:

Students...

Band 1-2	Band 3-4	Band 5-6
	Students complete a glossary for regulation of scientific research. The glossary requires students to define a word and then use the word within a sentence. (this glossary is designed to be completed throughout the module) Glossary Scientific regulation and ethics AFL: Students explore the need for regulation of scientific research through a jigsaw activity. Students work are allocated a topic and work in a group. Biotechnology Jigsaw Activity Students break into groups and present their information in round table discussions, giving knowledge as 'experts'. Students take notes for all topics presented.	Unfamiliar scenario and apply knowledge

Students Explain:

Students...

Band 1-2	Band 3-4	Band 5-6
	Teacher instructs students using Biotechnology slides 9 - 17 on how to use the IDEA acronym to explain the need for regulation of scientific research.	

Students Elaborate:

Band 1-2	Band 3-4	Band 5-6
	1. Evaluate the need for the regulation of scientific research 2. Assess ethical issues surrounding current scientific research 3. Assess a range of international scientific codes of conduct in regard to scientific research and practice 4. Evaluate the effectiveness of international regulation in scientific research and practice	

For each of the above, students are to use a different biotech research topic they have learnt about.

Students Evaluate (AOL, AAL, AFL)

Students

Band 1-2	Band 3-4	Band 5-6
	AOF: Students are to use the marking rubric to self assess the answers they have given. Teacher will collect students work, and mark 1 of the questions, giving the student feedback according to the rubric.	
Exemplar:	Exemplar:	Exemplar:

Additional resources and activities

Impact of regulatory science on global public health

What is a genome? | Facts | yourgenome.org What is DNA? | Facts | yourgenome.org What is a gene? | Facts | yourgenome.org

The ethics of using genetic engineering for sex selection | Journal of Medical Ethics Genes and Identity: Human Genetic Engineering | Learn Science at Scitable

The CRISPR-baby scandal: what's next for human gene-editing Genetic Technologies and Ethics

The CRISPR-baby scandal: what's next for human gene-editing https://www.labxchange.org/library/items/lb:LabXchange:b36cd4d0:html:1

https://www.labxchange.org/library/items/lb:LabXchange:900bd4e2:video:1 Australian gene-editing rules adopt 'middle ground'

Gene-edited babies: What does the law allow in Australia? | Pursuit by The University of Melbourne

Types of law - Parliamentary Education Office Delegated law - Parliamentary Education Office Making a law - Parliamentary Education Office Glossary - Parliamentary Education Office

Is selecting better than modifying? An investigation of arguments against germline gene editing as compared to preimplantation genetic diagnosis | BMC Medical Ethics | Full Text

Key Ethical Issues in Embryonic Stem Cell Research – Parliament of Australia

Biological Weapon | Britannica Biological weapons

Genetic engineering and biological weapons

Genetic engineering and biological weapons

Drug development: the journey of a medicine from lab to shelf - The Pharmaceutical Journal Inside Clinical Trials: Testing Medical Products in People | FDA

Testing of the rapeutic goods

Nuclear Definition & Meaning - Merriam-Webster

Nuclear industry definition and meaning | Collins English Dictionary The Many Uses of Nuclear Technology

What is Radiation? | ANSTO

Radioisotope uses for food and agriculture - World Nuclear Association Radioisotopes in Medicine

Nuclear-Powered Ships | Nuclear Submarines

Australian electricity options: nuclear – Parliament of Australia What is Radiation? | ANSTO

Radioisotope uses for food and agriculture - World Nuclear Association Radioisotopes in Medicine

Nuclear-Powered Ships | Nuclear Submarines BfS - What is the point of radiation research? Nuclear research | IAEA

Fact Sheet: What is Nuclear Medicine and Molecular Imaging? - SNMMI https://www.britannica.com/technology/nuclear-weapon

Nuclear Energy Agency (NEA) - Australia

Types of law - Parliamentary Education Office Delegated law - Parliamentary Education Office Making a law - Parliamentary Education Office Glossary - Parliamentary Education Office

World Nuclear Association Charter of Ethics

Ethic Definition & Meaning - Merriam-Webster

What is Indigenous cultural intellectual property and copyright and how can I respect it? - ABC News Indigenous Cultural and Intellectual Property (ICIP) - Arts Law Centre of

Indigenous Knowledge IP Hub | IP Australia

<u>Indigenous Cultural and Intellectual Property (ICIP) - Arts Law Centre of Australia</u>

Ethic Definition & Meaning - Merriam-Webster

Aboriginal Cultural and Intellectual Property (ACIP) Protocol Our Culture, Our Future | Terri Janke and Company

Protocols For Using First Nations Cultural And Intellectual Property In The Arts - Australia Council for the Arts

Appendix E - Overview of International Human Embryonic Stem Cell Laws Appendix: State Laws on Human Cloning

Surrogacy Act 2010

3

Fact sheet - How are genetically modified organisms (GMOs) regulated in Australia?

Ethical guidelines for organ transplantation from deceased donors

https://pursuit.unimelb.edu.au/articles/gene-edited-babies-what-does-the-law-allow-in-australia

https://www.abc.net.au/news/science/2019-04-30/crispr-gene-editing-in-the-food-chain/11053622

https://www.science.org.au/support/analysis/reports/synthetic-gene-drives-australia-implications-emerging-technologies/current

https://www.medicinesaustralia.com.au/code/about-the-code/

https://www.nps.org.au/consumers/how-medicines-are-approved-for-use-in-australia#medicines-regulation-and-clinical-trials

https://www.medicalboard.gov.au/codes-guidelines-policies/code-of-conduct.aspx

https://www.ifpma.org/wp-content/uploads/2016/01/Code of Conduct of the Pharmaceutical Industry in Switzerland 2013 English.pdf

https://peh-med.biomedcentral.com/articles/10.1186/1747-5341-9-7/tables/2

https://www.mass.gov/service-details/background-information-about-the-pharmaceutical-code-of-conduct#:~:text=The%20purpose%20of%20the%20code,adv ersely%20affect%20patient%20care%2C%20and

https://www.medicalradiationpracticeboard.gov.au/Registration-Standards/Code-of-conduct.aspx https://aanms.org.au/wp-

content/uploads/2021/06/AANMS CodeofConduct 18June2021.pdf

https://www.health.govt.nz/system/files/documents/publications/code-practice-nuclear-medicine-apr19.pdf

https://libguides.okcu.edu/c.php?g=225265&p=1492830

https://www.wipo.int/wipo magazine/en/2020/04/article 0006.html

Ethics of Biotechnology

Genetic modification of sex cells and embryos

Use the <u>learning pathway</u> link and your own research, to provide information to the following areas and be prepared to present to the rest of the class, remember you will be the expert.

Define genetic modification
Define of sex cells:
Define embryo:
Why do people use genetic modification of sex cells or embryos
List the technologies used to conduct genetic modification of cells or embryos
Describe CRISP-R Cas9
Describe how the technology works?
What regulations surround genetic modification of sex cells or embryos?
Define the word 'law':
What does the word 'regulation' mean?
What does the word 'Act' mean? In relation to the law.
Define the word 'legislation'.
What is the difference between an 'Act' and 'legislation':
What two pieces of legislation cover genetic modification of embryos in Australia?

What are some of the ethical considerations of gene modification of sex cells and embryos?				
Define the term 'ETHICS'?				
What are the benefits of gene modification of sex cells	What are the benefits of gene modification of sex cells and embryos?			
What are the disadvantages of gene modification of sea	x cells and embryos?			
What are the scientific codes of conduct and regulations modification of sex cells and embryos	in regard to scientific practice in the area of Genetic			
Define the term code of conduct.				
List Australian codes of conduct for Genetic mod	List Australian codes of conduct for Genetic modification of sex cells and embryos			
List international codes of conduct for Genetic modification of sex cells and embryos				
Describe codes of conduct and regulations for the area of Genetic modification of sex cells and embryos referencing both Australian and International codes of conduct				
List the advantages and disadvantages of codes of conduct in the chosen area				
Advantages	Disadvantages			

Testing of pharmaceuticals Use the <u>learning pathway</u> link provided and your own research, to provide information to the following
areas and be prepared to present to the rest of the class, remember you will be the expert.
Define pharmaceuticals
How are pharmaceuticals tested?
Why is it important to test pharmaceuticals?
How is pharmaceutical testing conducted?
What regulations surround pharmaceutical testing?
Define the word 'law':
What does the word 'regulation' mean?
What does the word 'Act' mean? In relation to the law.
Define the word 'legislation'.
What is the difference between an 'Act' and 'legislation':
What two pieces of legislation cover pharmaceutical testing in Australia?

What are some of the ethical considerations of **pharmaceutical testing**?

Define the term 'ETHICS'?

What are the benefits of **pharmaceutical testing**?

What are the disadvantages of **pharmaceutical testing**?

What are the scientific codes of conduct an	d regulations in regard to	scientific practice in the	ne area of testing of
pharmaceuticals			
Define the term code of conduct.			

List Australian codes of conduct for Testing of pharmaceuticals.

List international codes of conduct for Testing of pharmaceuticals

Describe codes of conduct and regulations for the area of pharmaceuticals referencing both Australian and International codes of conduct

List the advantages and disadvantages of codes of conduct in the chosen area

Advantages	Disadvantages

Products and processes of the nuclear industry, and uses of radiation
Use the <u>learning pathway</u> link provided and your own research, to provide information to the following areas and be prepared to present to the rest of the class, remember you will be the expert.

Define
Nuclear
Industry
Radiation
List the products and process of the nuclear industry
List the uses of radiation
Describe one of the processes of the nuclear industry
Describe the uses of radiation
What regulations surround the nuclear industry and the use of radiation?
Define the word 'law':
What does the word 'regulation' mean?
What does the word 'Act' mean? In relation to the law.
Define the word 'legislation'.
What is the difference between an 'Act' and 'legislation':

Regulations that surround the nuclear industry		
Regulations that surround the use of radiation		
What are some of the ethical considerations of using the	nuclear industry and using radiation?	
Define the term 'ETHICS'?		
What are the benefits of the nuclear industry and usi	ng radiation?	
What are the disadvantages of the nuclear industry and using radiation?		
What are the scientific codes of conduct and regulations in regard to scientific practice in the area of the nuclear industry and the use of radiation?		
Define the term code of conduct.		
List Australian codes of conduct for the nuclear industry and using radiation.		
List international codes of conduct for nuclear industry and using radiation.		
Describe codes of conduct and regulations for the area of Nuclear industry and the use of radiation referencing both Australian and International codes of conduct		
List the advantages and disadvantages of codes of conduct in the chosen area		
Advantages	Disadvantages	

Protection of Indigenous cultural and intellectual property.

Use the <u>learning pathway</u> link provided and your own research, to provide information to the following areas and be prepared to present to the rest of the class, remember you will be the expert.

Define Indigenous
What is meant by the term intellectual property?
what is meant by the term intellectual property:
What is indigenous cultural intellectual property"?
What does Indigenous cultural intellectual property (ICIP) include?
What is copyright?
ICIP rights are based in customary laws which are not recognised by the legal system. Why is this important for Indigenous cultural and intellectual property?
Can people use Indigenous cultural and intellectual property without permission? What is the consequence of this?
Extra information:
What regulations surround the protection of indigenous cultural and intellectual property?
Define the word 'law':
What does the word 'regulation' mean?
What does the word 'Act' mean? In relation to the law.
Define the word 'legislation'.
What is the difference between an 'Act' and 'legislation':
What pieces of legislation that cover indigenous cultural and intellectual property in Australia?
What are some of the ethical considerations of indigenous cultural and intellectual property?
Define the term 'ETHICS'?
ICIP not covered under legislation in Australia, what does this mean?

Indigenous cultural and intellectual property?	
What are the scientific codes of conduct and regulations in regard to scientific practice in the Protection	ı of

Define the term code of conduct.

List Australian codes of conduct for the protection of Indigenous cultural and intellectual property.

List international codes of conduct for the protection of Indigenous cultural and intellectual property

Describe codes of conduct and regulations for the area of Protection of Indigenous cultural and intellectual property referencing both Australian and International codes of conduct

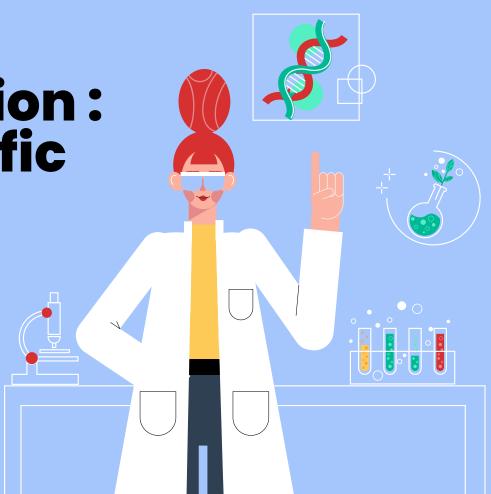
List the advantages and disadvantages of codes of conduct in the chosen area

Advantages	Disadvantages

Word	
Ethic	Definition:
	Sentence:
Research	Definition:
	Sentence:
Regulation	Definition:
	Sentence:
Biotechnology	Definition:
	Sentence:
Code of Conduct	Definition:
	Sentence:
Ethics	Definition:
	Sentence:
Genetics	Definition:
	Sentence:
Engineering	Definition:
	Sentence:
Pharmaceuticals	Definition:
	Sentence:
Indigenous	Definition:
	Sentence:
Bioprospecting	Definition:
	Sentence:
Intellectual property	Definition:
property	Sentence:



Inquiry Question: Why is scientific research regulated?



Learning intentions and success criteria

Learning Intentions:

I am learning why scientific research is regulated

So that I can...

- Investigate the need for regulation of scientific research.
- Investigate and assess ethical issues surrounding current scientific research
- Investigate a range on intentional codes of conduct in regards to scientific research and practice
- Evaluate the effectiveness of international regulation in scientific research and practice.

Success Criteria:

I can...

- **Explain** the need for regulation of scientific regulation
- **Explain** and assess the ethical issues surrounding scientific research
- Compare and contrast a range of international scientific codes of conduct in regards to scientific research
- **Evaluate** the effectiveness of international regulation in scientific research and practice



Definition concepts



Research

Research is the systematic investigation into and study of materials and sources in order to establish facts and reach new conclusions





Regulation

A regulation is a rule or directive made and maintained by an authority.



Ethics can be defined as the moral principles that govern a person's behaviour or the conducting of an activity.





Biotechnology

Biotechnology is technology that utilizes biological systems, living organisms or parts of this to develop or create different products

Definition concepts



Code of conduct

Are the principles, standards, and the moral and ethical expectations that employees and third parties are held to as they interact within an organization.



Research

the systematic investigation into and study of materials and sources in order to establish facts and reach new conclusions.



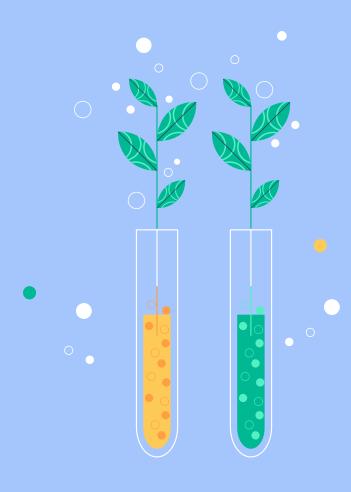
a rule or directive made and maintained by an authority.





Ethics

Ethics can be defined as the moral principles that govern a person's behaviour or the conducting of an activity.



What do you think you know about regulating scientific research?

What is scientific research?

What do you know about scientific research?

How does scientific research affect you everyday?

Is scientific research a positive or negative thing?

Why is it important for scientific research to be regulated?

What does regulation mean and why is it needed for scientific research?

A regulation is a rule or directive made and maintained by an authority.

So this means that, a regulation is a set of rules set by an authority to ensure that a person or group is conducting themselves correctly.

Regulation is important within scientific research because it protects public health world wide, by ensuring that food and medical products are safe, properly labeled, and effective.







Investigating the need for regulation of scientific research, for example:

- Genetic modification of sex cells and embryos
- Testing and research of pharmaceuticals
- Products and processes of the nuclear industry, and uses of radiation
- Protection of Indigenous cultural and intellectual property, with reference to bioprospecting and mining







Jigsaw activity

Students undertake a jigsaw activity. Students split into groups and use the information provided and their own research, to gather information and present back to the class on their given topic and the need for scientific regulations surrounding:

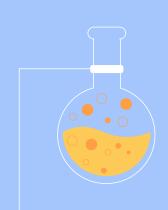
- Genetic modification of sex cells and embryos
- Testing and research of pharmaceuticals
- Products and processes of the nuclear industry, and uses of radiation
- Protection of Indigenous cultural and intellectual property,
 with reference to bioprospecting and mining







Present information









- Evaluate the need for the regulation of scientific research
- Assess ethical issues surrounding current scientific research
- Assess a range of international scientific codes of conduct in regard to scientific research and practice
- 4. Evaluate the effectiveness of international regulation in scientific research and practice

Use a different example for each question







But first ...

HOW DO YOU DO THIS?





Use IDEA!

I - identify

D - describe

E - explain

A - assess





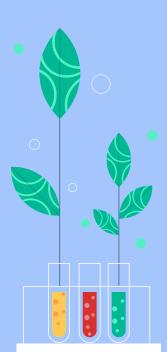
Identify ...

The first step is to indicate what you are going to explain.

For example:

Biotechnology is subject to **scientific regulations** which encompasses laws and regulations made by governments and academic institutions, that guide scientific researchers in what they are allowed to do and what they are restricted from doing.





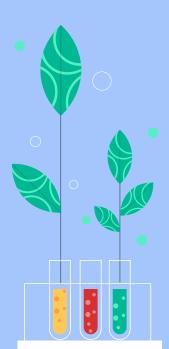
Describe ...

To describe something is to state or give an account of what something is.

For example: development of biotechnology and gene manipulation.



Biotechnology is technology that utilizes biological systems, living organisms or parts of, to develop or create different products. **Gene manipulation** can either be direct (by manipulating one or more genes) or indirect (through selective breeding).



Explain ...

Explain relates the cause to the effect.

What is the cause (why does this happen) - Link - What is the effect (what happens)

For example:

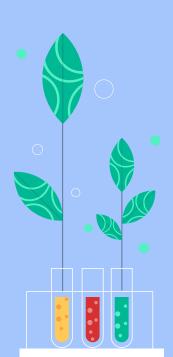


Cause	Link	Effect
The muffins at the canteen are cheap	so	Everyone buys them
Gravity was acting on the cart	therefore	It rolled down the ramp
I applied a large force to the soccer ball	Consequently	It went a long way

How to **Explain** in science

- **1. WHAT**... Identify the issue (what material are you using in your filter?).
- 2. **CAUSE**...Identify the reasons (How is the material used in the filter?)
- 3. Link.... Use words like: so, therefore, consequently
- 4. **EFFECT**... Identify the outcome (What are the impacts on the filtrate?)





For example ...

Cause	Link	Effect
Biotechnology is the use of artificial methods	to modify	the genetic material of an organism to perform new functions.
Gene manipulation is the direct manipulation of one or more genes	in order to	change an organism or modify a population of organisms.
Biotechnology and gene manipulation are regulated	so that	the health and safety of the general public and the environment are protected, along with identifying and managing associated risks.



Assess ... State the effectiveness of something, giving a reason for the rating of effectiveness.

For example:

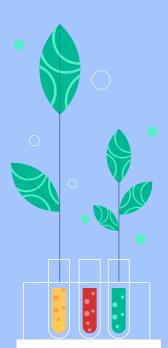
Biotechnology and gene manipulation should be regulated. The federal government of Australia has appointed a Regulator and an Ethics Community Committee who work under the Gene Technology Act 2000 to provide advice on subjects such as ethical issues, license applications in relation to GMO and general matters relating to biotechnology and gene manipulation. The regulation of biotechnology and gene manipulation is advantageous because it can prevent the risk of disease outbreaks, quarantine breaches, genetic engineering and food contamination, and ensures the integrity and suitability of tissues and organs used in research.



Final Explanation (this is an example paragraph)

Biotechnology is subject to scientific regulations which encompasses laws and regulations made by governments and academic institutions, that guide scientific researchers in what they are allowed to do and what they are restricted from doing. Biotechnology is technology that utilizes biological systems, living organisms or parts of, to develop or create different products. Gene manipulation can either be direct (by manipulating one or more genes) or indirect (through selective breeding). Biotechnology is the use of artificial methods to modify the genetic material of an organism to perform new functions. Gene manipulation is the direct manipulation of one or more genes in order to change an organism or modify a population of organisms. Biotechnology and gene manipulation are regulated so that the health and safety of the general public and the environment are protected, along with identifying and managing associated risks. Biotechnology and gene manipulation should be regulated. The federal government of Australia has appointed a Regulator and an Ethics Community Committee who work under the Gene Technology Act 2000 to provide advice on subjects such as ethical issues, license applications in relation to GMO and general matters relating to biotechnology and gene manipulation. The regulation of biotechnology and gene manipulation is advantageous because it can prevent the risk of disease outbreaks, quarantine breaches, genetic engineering and food contamination, and ensures the integrity and suitability of tissues and organs used in research.

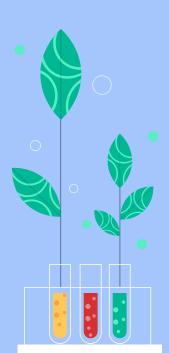




- 1. Evaluate the need for the regulation of scientific research
- 2. Assess ethical issues surrounding current scientific research
- 3. Assess a range of international scientific codes of conduct in regard to scientific research and practice
- 4. Evaluate the effectiveness of international regulation in scientific research and practice

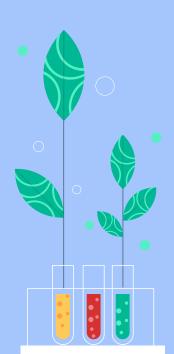
Use a different example for each question





Create rubric



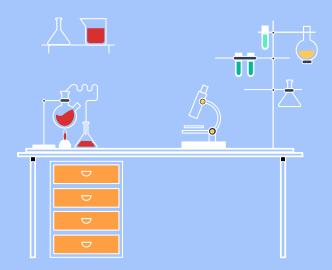


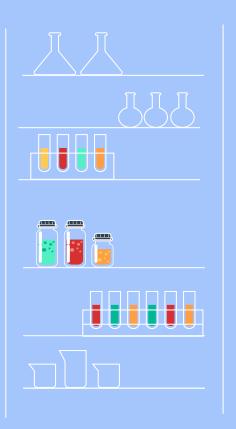
Biotechnology Icon Pack



Alternative resources

Here's an assortment of alternative resources within the same style of this template





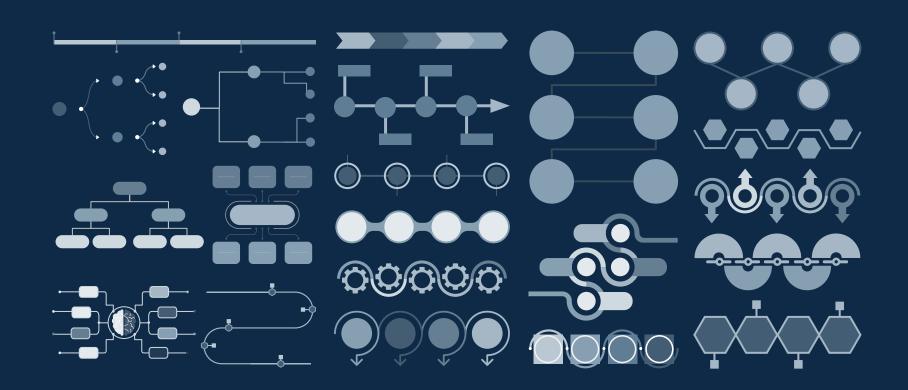
Use our editable graphic resources...

You can easily resize these resources without losing quality. To change the color, just ungroup the resource and click on the object you want to change. Then, click on the paint bucket and select the color you want.

Group the resource again when you're done. You can also look for more infographics on Slidesgo.









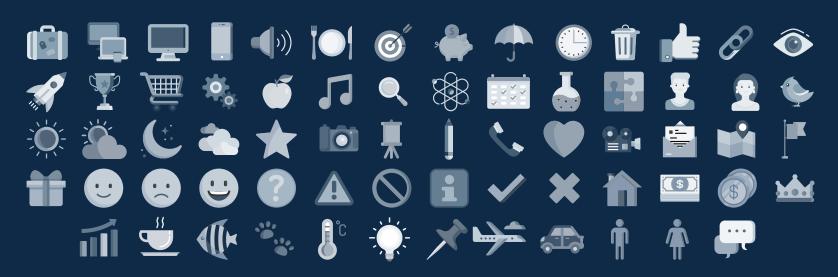




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Creative Process Icons



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