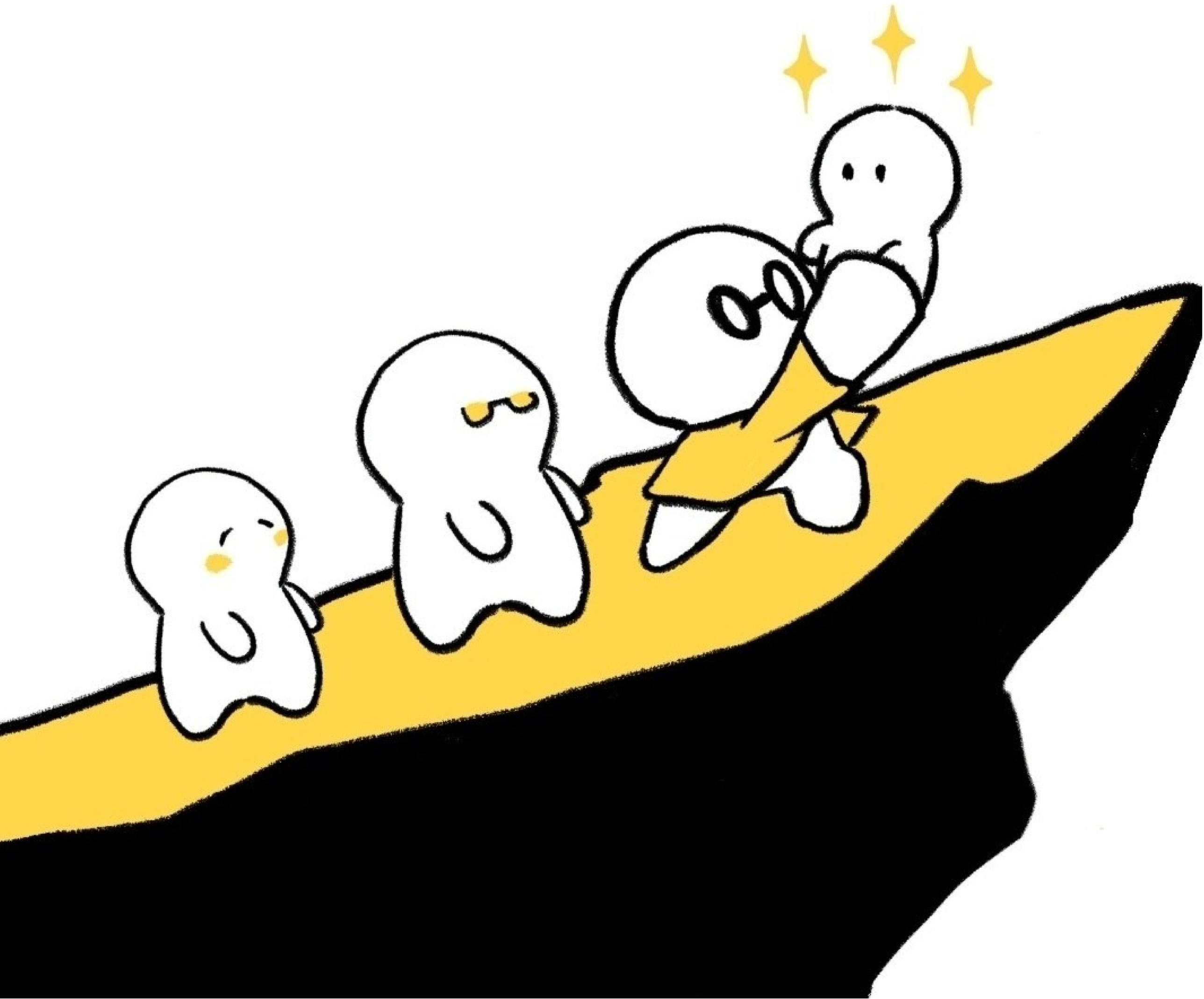
KEY HIGHLIGHTS FOR LAYPERSONS

The Key to Success for Laypersons on Research Ethics Committees/ Institutional Review Boards

Health Systems Research Institute (HSRI)
Ministry of Public Health, Thailand



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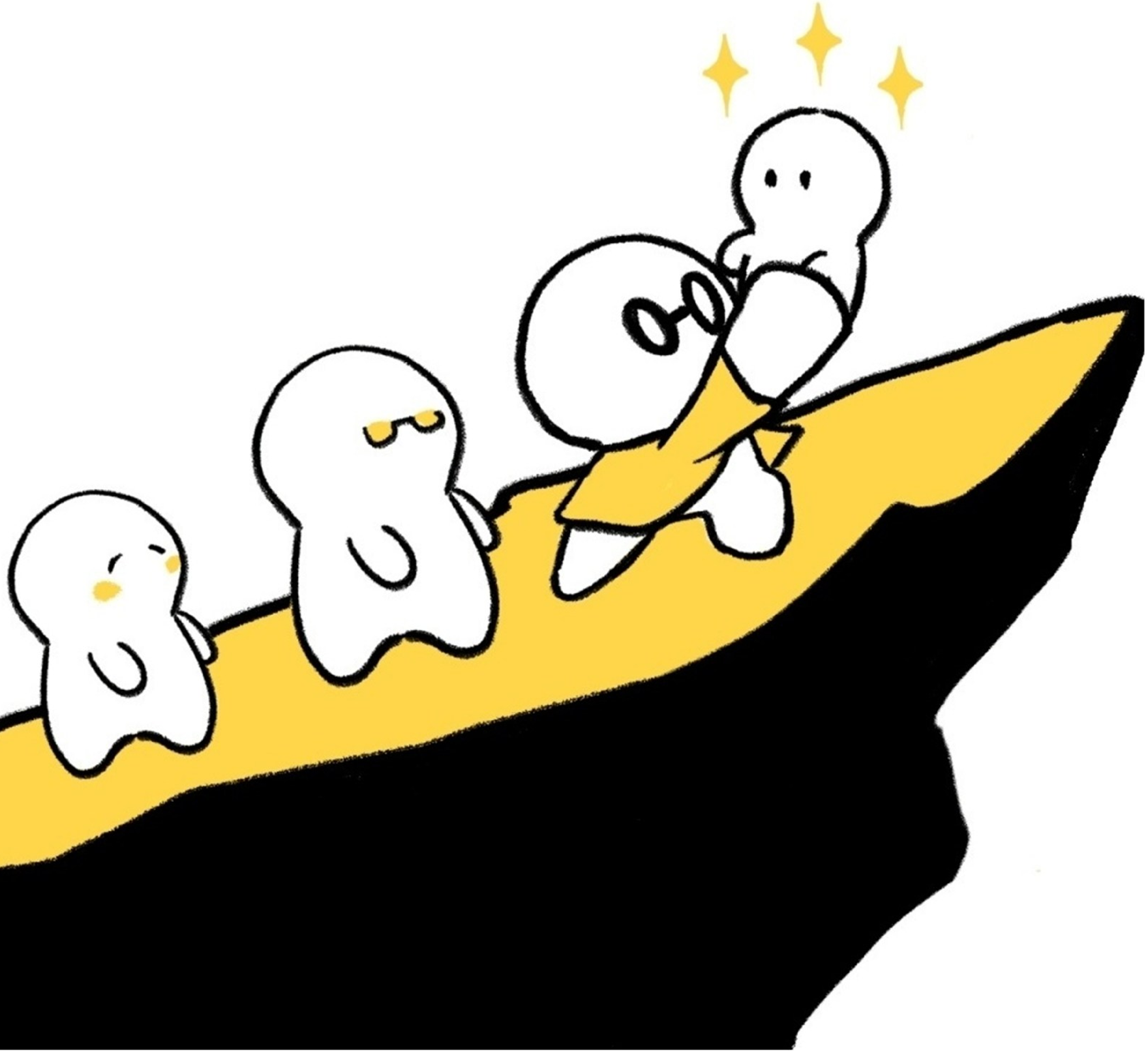

KEY HIGHLIGHTS FOR LAYPERSONS
The Key to Success for Laypersons
on Research Ethics Committees/
Institutional Review Boards

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INTRODUCTION

The Key to Success for Laypersons on Research Ethics Committees/Institutional Review Boards was developed with the support of the Health Systems Research Institute to enhance the capacity of public-sector representatives serving on research ethics committees and the institutional review board. Its primary aim is to support these members in effectively fulfilling their responsibilities in reviewing the ethical aspects of research involving humans, with the ultimate goal of ensuring the safety and protection of research participants throughout the research process.

Meaningful ethical review of human research relies on the inclusion of perspectives from committee members who represent the general public. These members provide valuable insights that reflect the viewpoints of research participants and offer an impartial perspective grounded in real-world experience and community context.

This book serves as a practical and accessible guide for public representatives. It outlines core ethical principles and presents practical strategies for evaluating critical issues in human research. Designed in a concise and easy-to-navigate format, it equips public committee members with the essential knowledge and tools needed for ethical review.

The authors hope this book will empower public representatives to conduct thorough, informed, and responsible evaluations of research proposals, thereby contributing to the ethical integrity of research and safeguarding the rights and well-being of all participants.

Production Team
Health Systems Research Institute and
SIDCER-FERCAP Foundation
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2nd edition

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Translation was performed using the Google Translate feature in Google Lens. Copyediting and proofreading were assisted by Microsoft Copilot AI and ChatGPT. The Futura Handwritten font, created by Billy Snyder, was downloaded from https://www.dafont.com/futurahandwritten.font?l[]=10&l[]=1 on 23 June 2025.

Dr. Alvin Concha
Dr. Nattharmma Namfah
2025

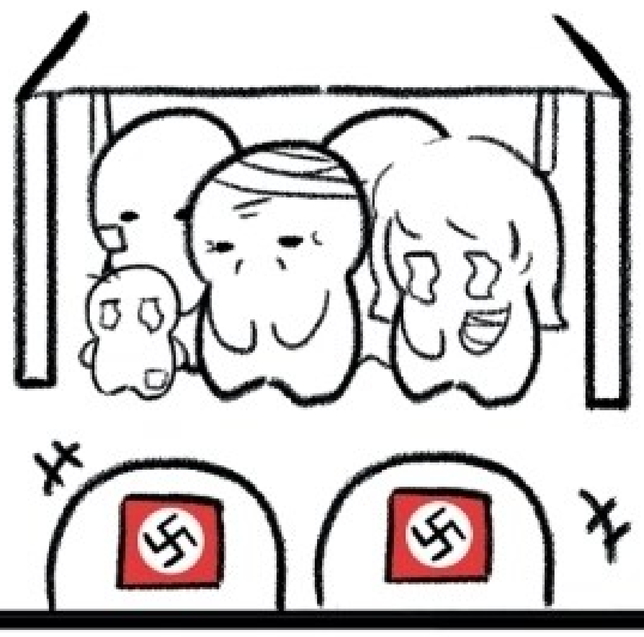
01

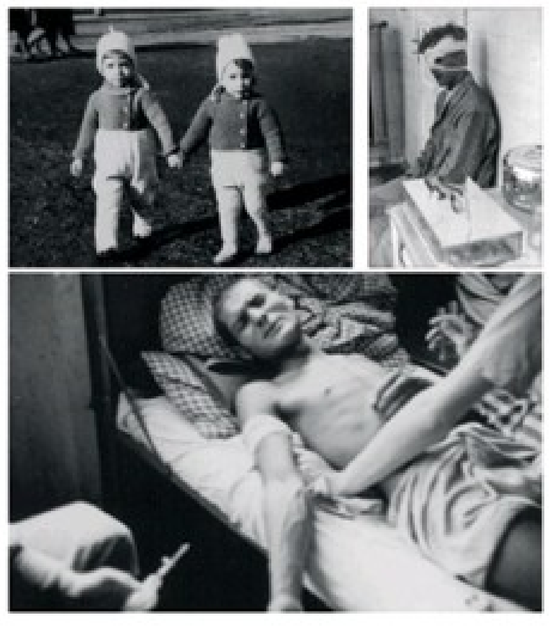
History, principles, international guidelines,
and legal frameworks in research ethics

Nuremberg Code 1947

The Origin of Informed Consent in Human Research

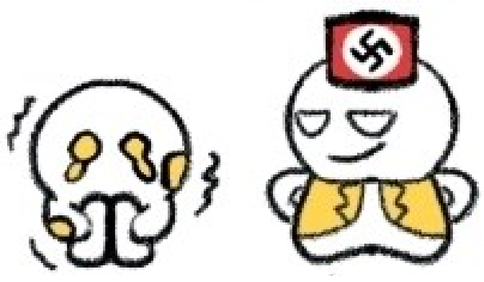
During World War II, the Nazi regime locked up many people in concentration camps. There, some were killed, while others were forced to go through painful and dangerous medical experiments.





After the war, soldiers discovered that people in the camps had been forced into painful medical experiments without their permission. Many were badly injured or died as a result. This tragic history reminds us how important it is to always respect every person's dignity and right to make their own choices.

Because these crimes were so serious, they were brought to court during the Nuremberg Trials in 1945 and 1946. Members of the Nazi regime were found guilty and punished. Some were sent to prison, while others were sentenced to death, depending on how severe their actions were.



Investigations after the war revealed the Nazi regime's cruel medical experiments, which caused many deaths and injuries. As a result, the Nuremberg Code was created in 1947, listing 10 key principles to ensure research is done ethically and with respect for human rights.

The main principles are:

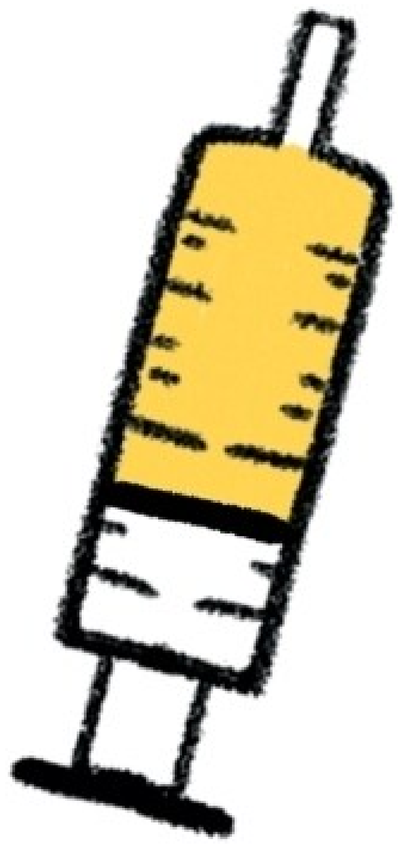
- the requirement for informed consent
- a fair balance between risks and benefits for research participants, and
- the participants' right to withdraw from the study at any time.

Declaration of Helsinki

Why is it more important to protect the rights and well-being of people in research than to focus only on the new knowledge we might gain from the study?

1963

At a Jewish hospital in New York City, researchers once carried out an experiment where they injected cancer cells into patients who were already very sick, to see if their bodies would fight off the cancer. However, the researchers did not tell the patients what they were doing because they were afraid the patients would be upset or refuse to take part.

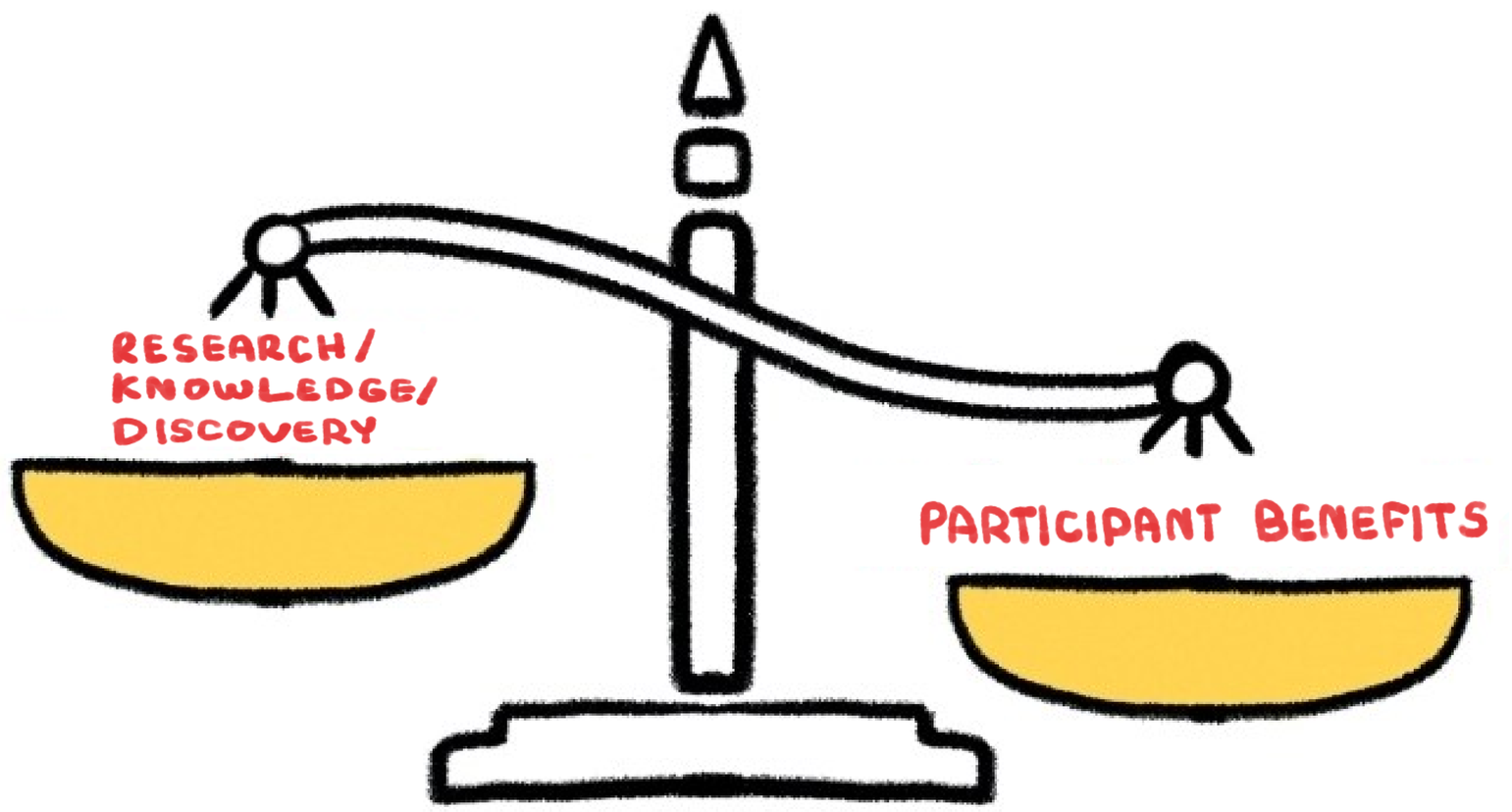


Declaration of Helsinki

1956 – 1971

After noticing that people who survived hepatitis became immune, researchers started a vaccine experiment at Willowbrook State School, a facility for children with intellectual disabilities in New York. Because hepatitis was common at the time, they saw this research as urgent. However, to study how the body reacts, they deliberately exposed the children to the virus—either through injections or contaminated food. The children and their parents were not fully told what would happen or what the risks were.

Declaration of Helsinki



2000 Edition, Section 5

"In medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society."

2013 Edition, Section 8

"While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects."

2024 Edition, Section 7

"The primary purpose of medical research involving human participants is to generate knowledge to understand the causes, development and effects of diseases; improve preventive, diagnostic and therapeutic interventions; and ultimately to advance individual and public health. These purposes can never take precedence over the rights and interests of individual research participants."

The Belmont Report 1979

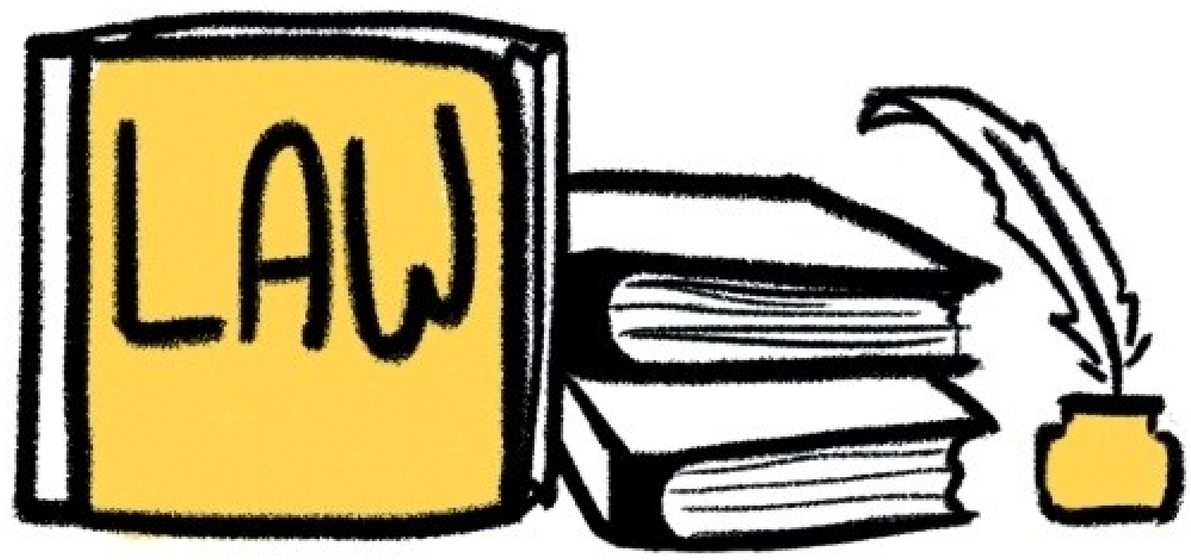
Why we have research ethics committees today

Tuskegee syphilis research 1932-1972

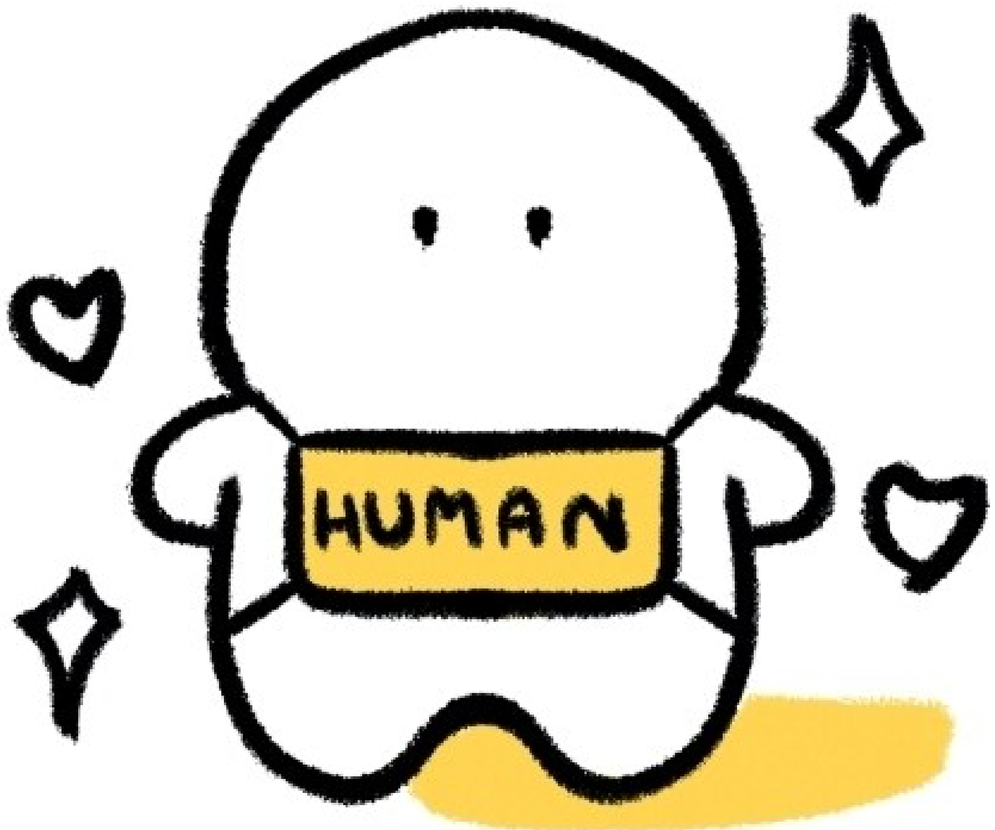
In 1972, *The New York Times* revealed the Tuskegee Syphilis Study—a government-run experiment that secretly studied the effects of untreated syphilis. The study involved 600 poor African American men, but they were never told they had the disease and were not given treatment. Instead, they were offered free meals and funeral costs in return for joining the study and allowing their bodies to be examined after death. Even after a cure for syphilis was found, the researchers chose not to treat them, letting the disease continue to harm them. Many of the men suffered serious health problems like blindness, heart issues, brain damage, and even death.

The study lasted for 40 years, from 1932 to 1972.

The Belmont Report 1979

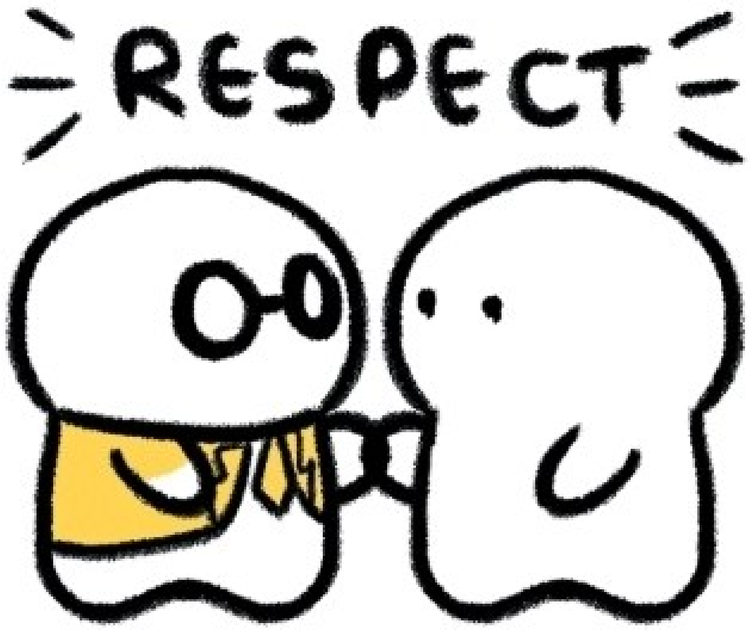


In response, the United States passed the National Research Act in 1974 to help protect people in research studies. The law required all institutions doing human research to set up Institutional Review Boards (IRBs)—groups that review and monitor studies to make sure they are ethical and safe for participants.



Later, in 1979, the Belmont Report was introduced. It explained the main principles for doing ethical research with people and gave clear guidelines to help decide if a study follows those rules. This report played a big role in updating U.S. research laws in 1981 to better protect participants.

The Belmont Report 1979



1. **Respect for persons**
- Everyone should be treated with dignity and allowed to make their own choices
- People who cannot fully make decisions for themselves need extra protection

2. **Beneficence**
- Do no harm, minimize the risk of harm
- Maximize possible benefits

3. **Justice**
- Ensure fair distribution of risks and benefits.

CIOMS 1982-2016

(Council for International Organizations of Medical Sciences)

Should research ethics standards be the same in rich and poor countries? How?

In 1982, the CIOMS organization noted that researchers from wealthier countries often carry out studies or gather data from people in poorer, developing countries.

To stop unfair treatment, CIOMS created guidelines to make sure research is done ethically. These rules aim to prevent researchers from taking advantage of people in developing countries—like using them in studies without giving them the protection and respect they deserve.

CIOMS updated its guidelines in 1993 and 2002, mainly because of research on drugs and vaccines to fight AIDS. These studies raised important questions about whether the same ethical rules used in rich countries should also apply in poorer countries. In response, new guidelines were made to ensure research is fair, respectful, and responsible no matter where it takes place.

Back then, this type of research was called 'biomedical research.' It involved studying parts of the human body, such as cells, tissues, and body fluids, as well as looking at medical records and personal health information.

CIOMS 2016

Expanding the scope of research beyond biomedicine to emphasize its scientific and social value

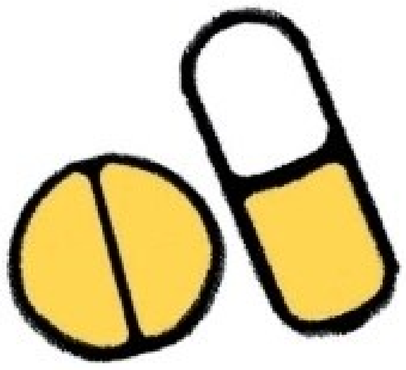
It is important to include vulnerable groups such as children, pregnant women, and people who cannot give consent in research when it is appropriate and safe. If they are always left out, there will not be enough research to understand and support their specific needs in the future.

Researchers should get broad informed consent if they plan to use data or biological samples in the future. This means setting up clear rules and protections that manage how the materials are used, instead of asking for permission each time. To respect participants' choices, there should also be a way for them to opt out if they do not want to take part.

Researchers and those who fund research should focus on studies that answer important questions or solve problems that have not been resolved. This helps make science more trustworthy and avoids doing research that is not useful, even if it does not seem harmful.

ICH GCP Guidelines 1996

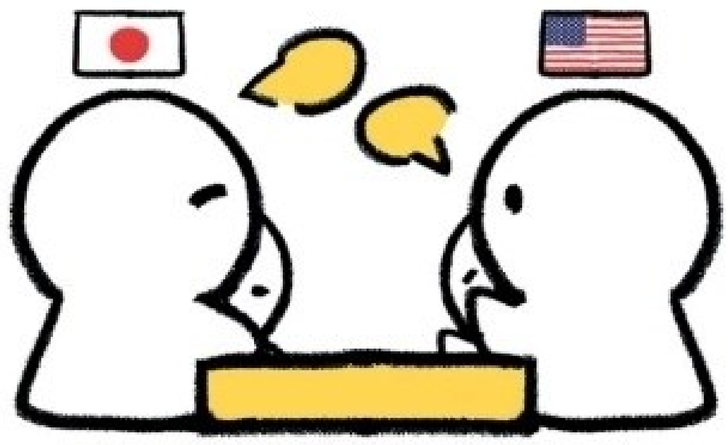
Why should drug and medical research follow the same global standards?



Before any medicine or medical product can be used in our country, it must first be registered to ensure user safety.

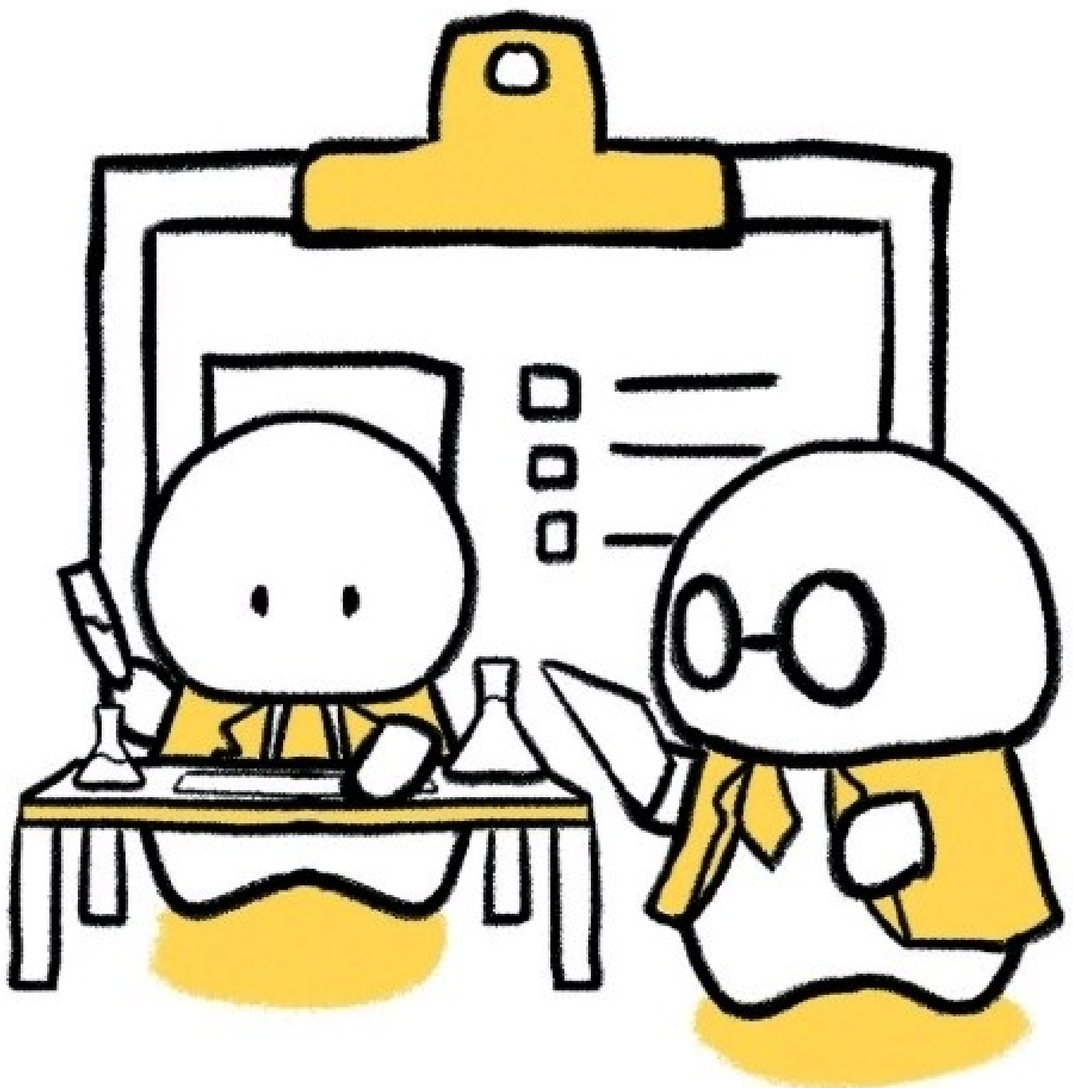
To register a medicine or medical product, manufacturers must submit clinical trial results to the government for review.

Because each country has its own standards, data from one country often cannot be used for registration in another, leading to delays in the process.



The United States, Europe, and Japan formed the International Conference on Harmonisation (ICH) to align differing Good Clinical Practice (GCP) standards and created 13 global principles.

ICH GCP Guidelines



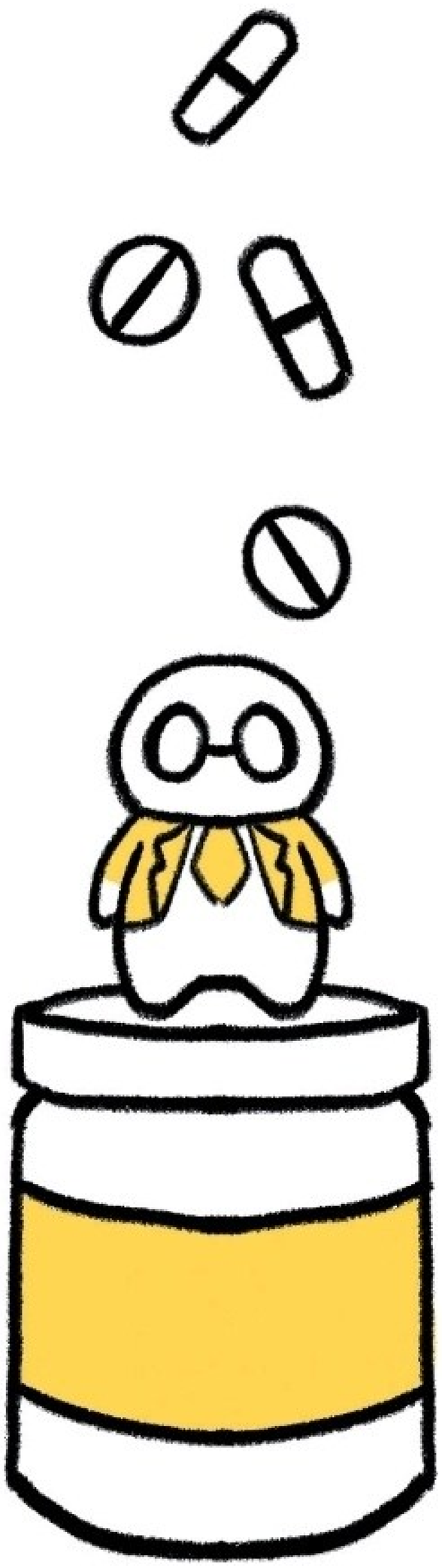
1996

- International ethical and academic standards for designing, conducting, recording, collecting data, and reporting human research studies

- Research must follow rules that protect the human rights, safety, and well-being of participants, based on the principles of the Declaration of Helsinki. The findings from clinical research must also be scientifically trustworthy.

- In 2016, ICH GCP was revised, and the organization's name changed from the International Conference to the International Council on Harmonisation.

- The ICH GCP was updated in 2025 to keep up with changes in how research is done today. The new version allows more flexibility and can be used with a wider variety of research methods. It highlights the importance of careful planning and thinking about the specific needs of each study to ensure high-quality research. The guidelines were also reorganized to make them clearer and easier to understand.



1999

- In human research, it is necessary to check for conflicts of interest. Researchers must share any personal or financial connections that could influence their study.

2004

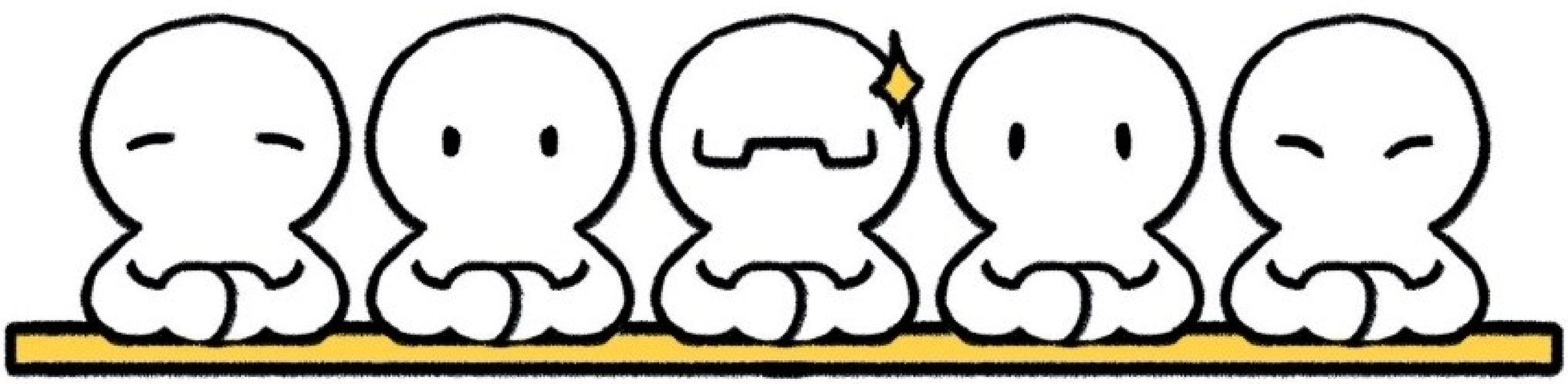
- Vioxx, a widely used painkiller in the U.S. and over 80 countries, was withdrawn after five years due to increased risks of heart attacks and strokes. The manufacturer pulled it from the market amid safety concerns.

- Academic journals and government agencies, such as the Food and Drug Administration, require researchers to register their projects and clinical trials on a website that the public can access.

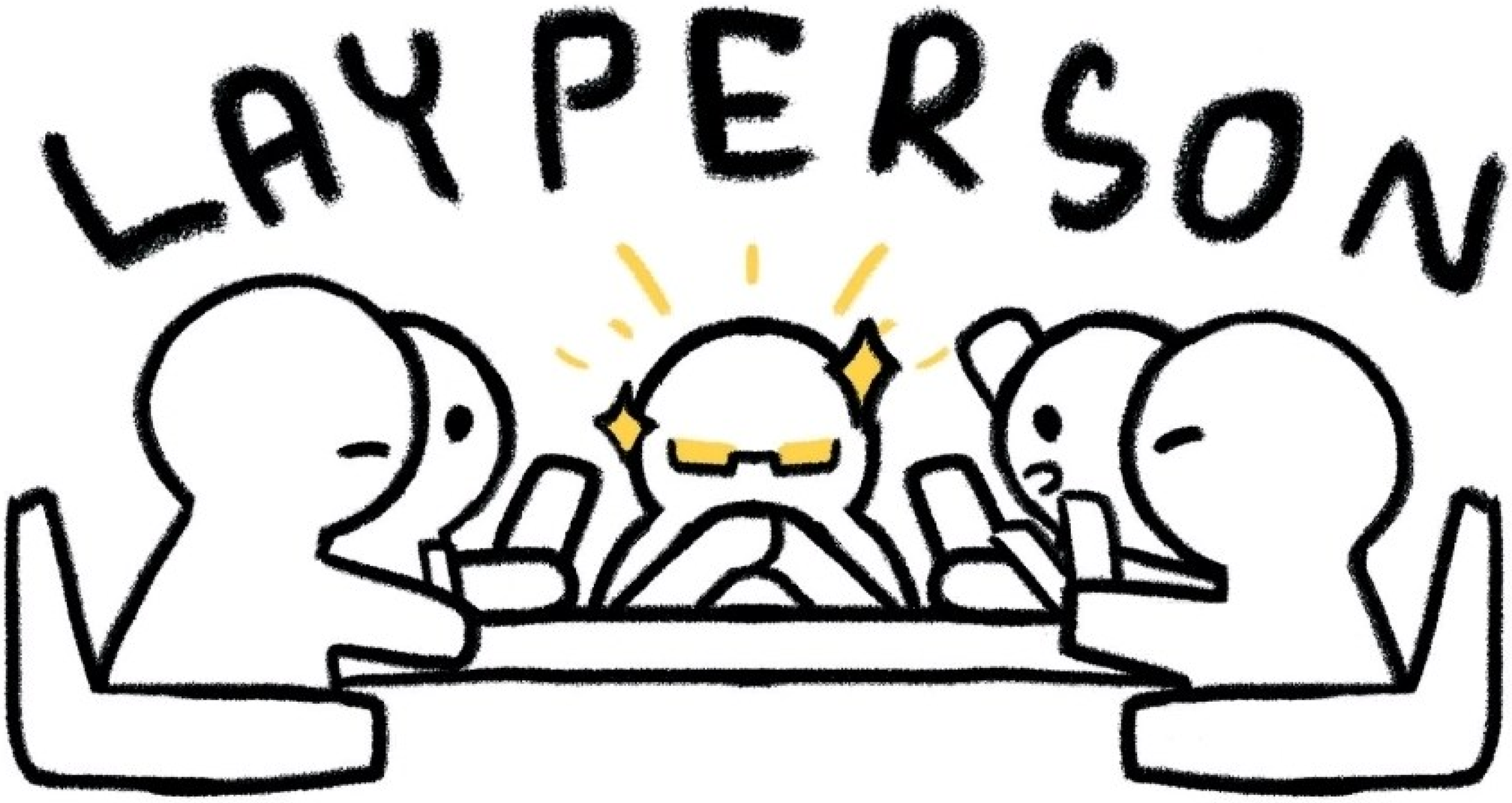
- The U.S. National Institutes of Health has made a rule that researchers cannot own shares in drug companies. This helps prevent conflicts of interest that might affect the results of a study or how the findings are reported.

These measures are meant to protect everyone who takes part in research. They help make sure participants are treated with respect, given the freedom to choose, treated fairly, and that the research benefits both science and public health.

02



Roles and responsibilities of laypersons in the research ethics committee



Let us start by understanding the role of the Institutional Review Board or Ethics Committee, also known as the IRB or EC. This group plays an important role in protecting people who take part in research. Every research project must be reviewed in a way that is open, careful, and based on strong ethical values. The review must be done independently, without pressure from the institution. The committee must have at least five members with a mix of genders, backgrounds, and ages. It must also include at least one person from outside the institution and at least one non-expert member or layperson.

Why is there a layperson on the IRB/EC?

A layperson is someone who is not a research expert. Their role is to give an independent opinion that reflects the views of the general public. International ethics guidelines require that every review committee includes a layperson. If a layperson is not present, the committee does not meet the minimum requirement and cannot continue with the review.

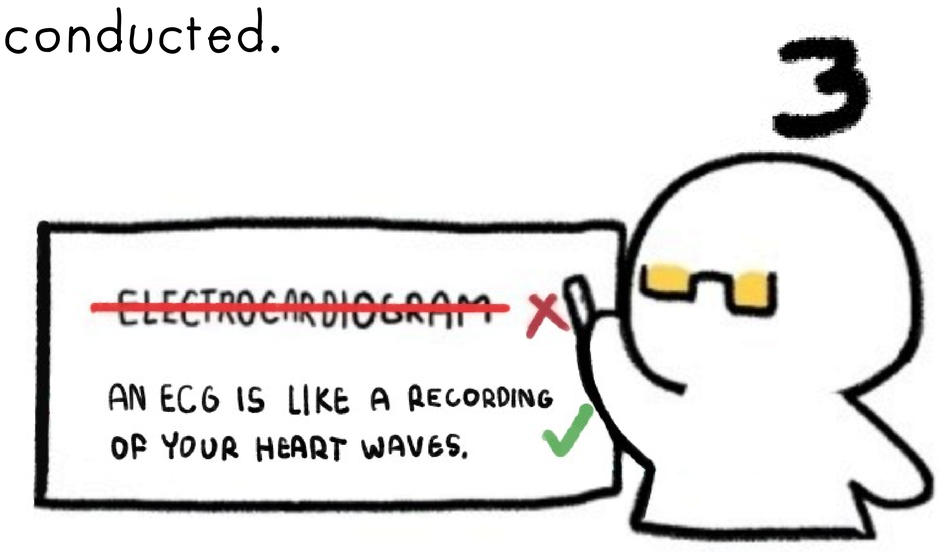
Who is a layperson?

A layperson is someone who is not a medical or research specialist and offers input on research projects from the perspective of the general public.

What should a layperson consider?

As members who represent the community, laypersons should think about whether the research project is helpful to both the participants and the community. They should look at possible risks to those involved and decide if the project gives everyone a fair chance to take part.

Laypersons should consider whether the consent process is appropriate—WHO obtains it, WHEN and WHERE it is obtained, and HOW it is conducted.



Laypersons should help simplify informed consent forms to remove overly technical terms and ensure they are clear and accessible to participants.

What does a layperson need to do?

Attend regular training on research ethics.

- Disclose any conflicts of interest to the IRB/EC and follow established procedures
- Review assigned documents
- Attend meetings as a representative of the general public
- Share your opinions
- Participate in voting

Maintain confidentiality and do not disclose or publish any information discussed or reviewed as part of the committee.

03

Guidelines for reviewing research projects involving vulnerable individuals or groups

Who is considered vulnerable?

People or groups who face a higher risk of being harmed or taken advantage of in research are seen as vulnerable. This is usually because they have limited ability to protect their own rights or make informed decisions. These individuals need extra care and protection in research.

In what situations are individuals or groups considered vulnerable, and what measures can be taken to protect them?

Cognitive or Communicative Vulnerability

People may be considered vulnerable if they have trouble making decisions or communicating clearly. This includes groups like children or individuals with limited understanding or awareness.

To protect vulnerable participants, certain steps may be taken. These include having a legal representative make decisions for the participant, getting joint agreement from both the participant and their guardian, providing documents in a language they can understand, including a neutral witness if the person cannot read or write, and asking for consent again if the person later becomes able to make their own decisions.

Institutional Vulnerability

People may be considered vulnerable if they are under pressure to obey orders, like soldiers or police officers, or if they live in places where their freedom is limited, such as prisons.

Their choice to join a research study must be made freely, without pressure from people in power. This is called giving voluntary consent.

Deferential Vulnerability

People may be considered vulnerable if they depend on someone in authority or are afraid to say no. This can include students or employees who feel pressured by teachers or supervisors.

Their decision to take part in research must be their own choice and not influenced by anyone in a position of power. This is known as voluntary consent.

Medical Vulnerability

People may be considered vulnerable if they are sick, especially if they have serious or incurable illnesses.

Researchers should give clear and accurate information, especially about any risks. They should make sure there is no misunderstanding about what the treatment can or cannot do. Participants should be given enough time to think it over and be encouraged to talk with their family or health care providers before deciding.

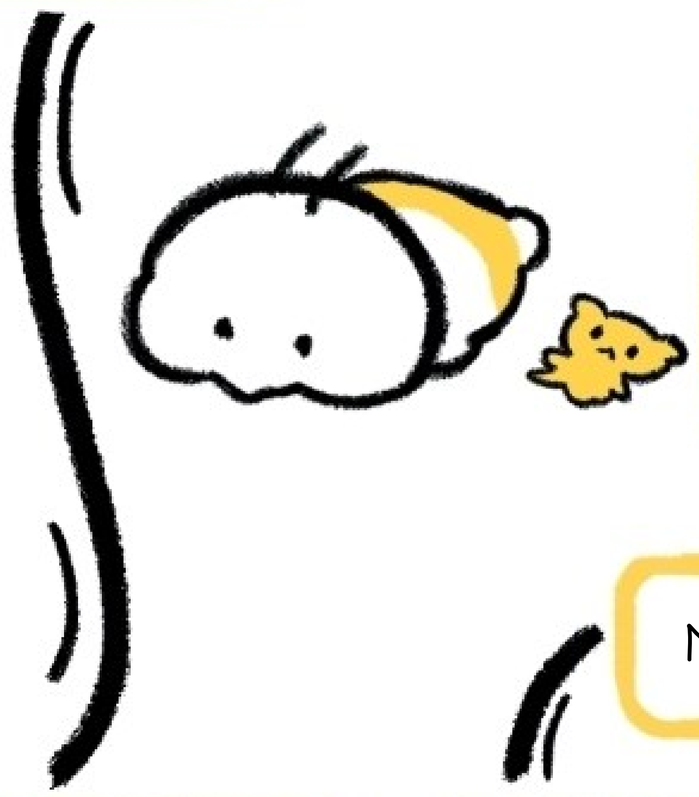
Economic vulnerability

People may be considered vulnerable if they are struggling with money or social problems. This can include those who have low income, little access to education, or are left out by society, such as people who are homeless.

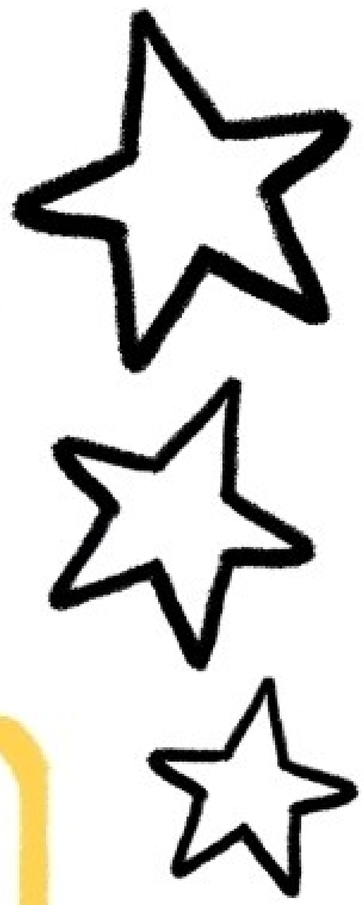
When giving information to people in difficult situations, researchers must explain everything clearly and gently so the person does not feel forced or pressured to join the study.

The necessity of conducting research involving vulnerable groups

The research is valuable and not feasible in non-vulnerable groups



The research is valuable, yet feasible in other groups



There are scientific reasons for excluding vulnerable participants from the research

No

Yes

Appropriate to conduct the research involving vulnerable groups

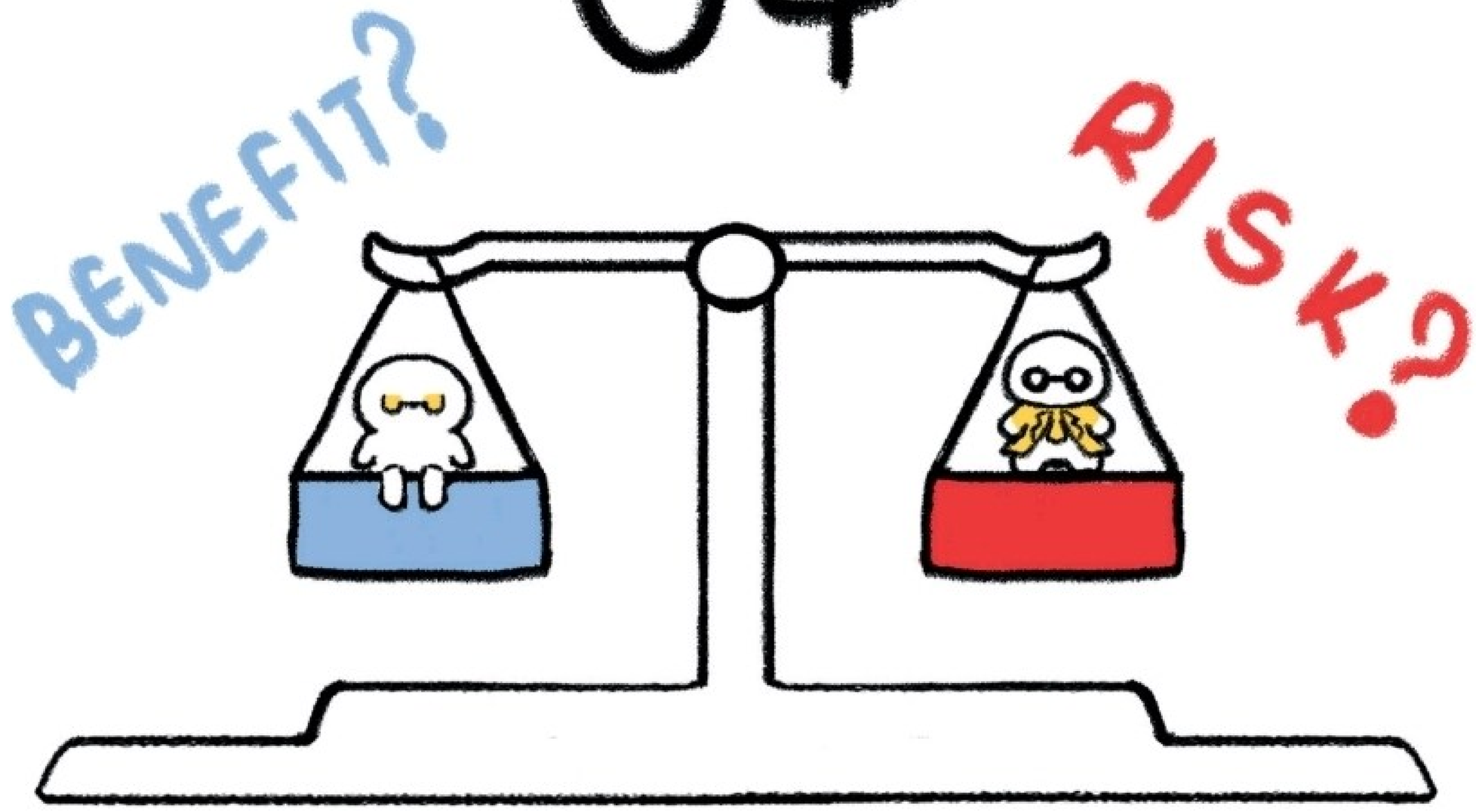
The research may be conducted involving vulnerable groups

Inappropriate to conduct the research involving vulnerable groups

Identify the cause or nature of the participants' vulnerability

Identify measures to protect or enhance the safety of vulnerable participants.

04



Risk and benefit assessment, risk minimization, and benefit maximization

Duties of public representatives

Identify risks

- From intervention
- From the research process
- From the environment, such as data leakage, unpreparedness of researchers

What are the potential consequences (harm, side effects, or discomfort) of participating in research?

Assess the severity and likelihood of risk

- Is it acceptable to the research participants?
- Are the participants adequately informed?
- Are the participants given sufficient information to make an informed decision?

- Is the risk high?
- Can the risk be minimized? (Risk reduction)
- Is the research beneficial?

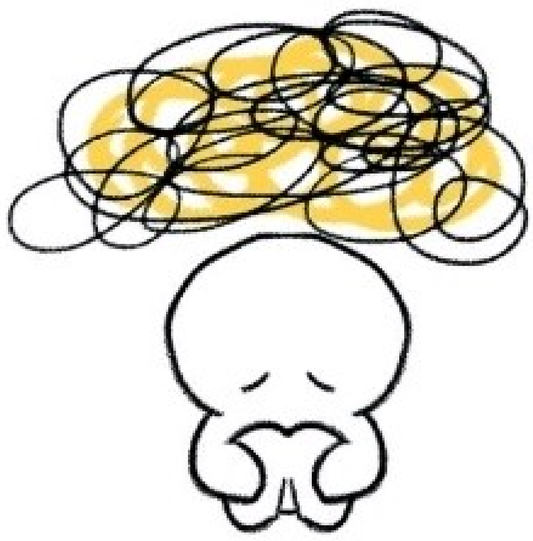
- Are participants adequately informed?
- How do the potential benefits compare to the risks?

Research projects can involve different types of risks

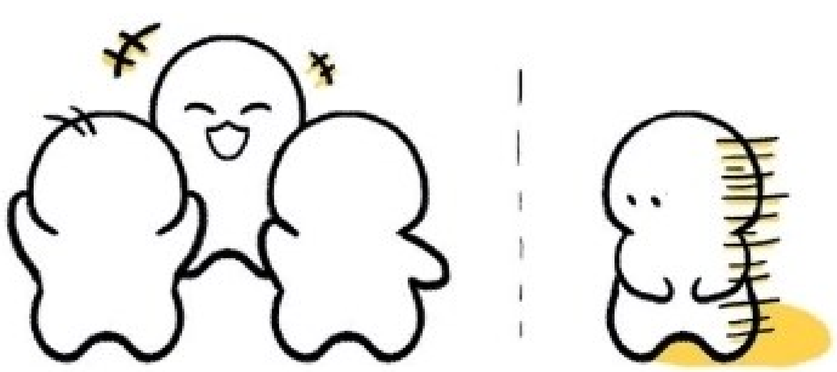
Expert reviewers look at each study to identify what risks might happen, how serious they could be, and how likely they are to occur

Physical risks
injury, discomfort, pain—such as from blood tests, fatigue, placebo use, elevated laboratory results, rashes

Psychological risks
sadness, anxiety, stress, uneasiness



Social risks
shame, stigma, discrimination, rejection by the community



Research projects can involve different types of risks
Expert reviewers look at each study to identify what risks might happen, how serious they could be, and how likely they are to occur

Economic risks
loss of employment, income, or opportunities

Legal risks
Being arrested or accused

Privacy risks
invasion of privacy or disclosure of personal or confidential information

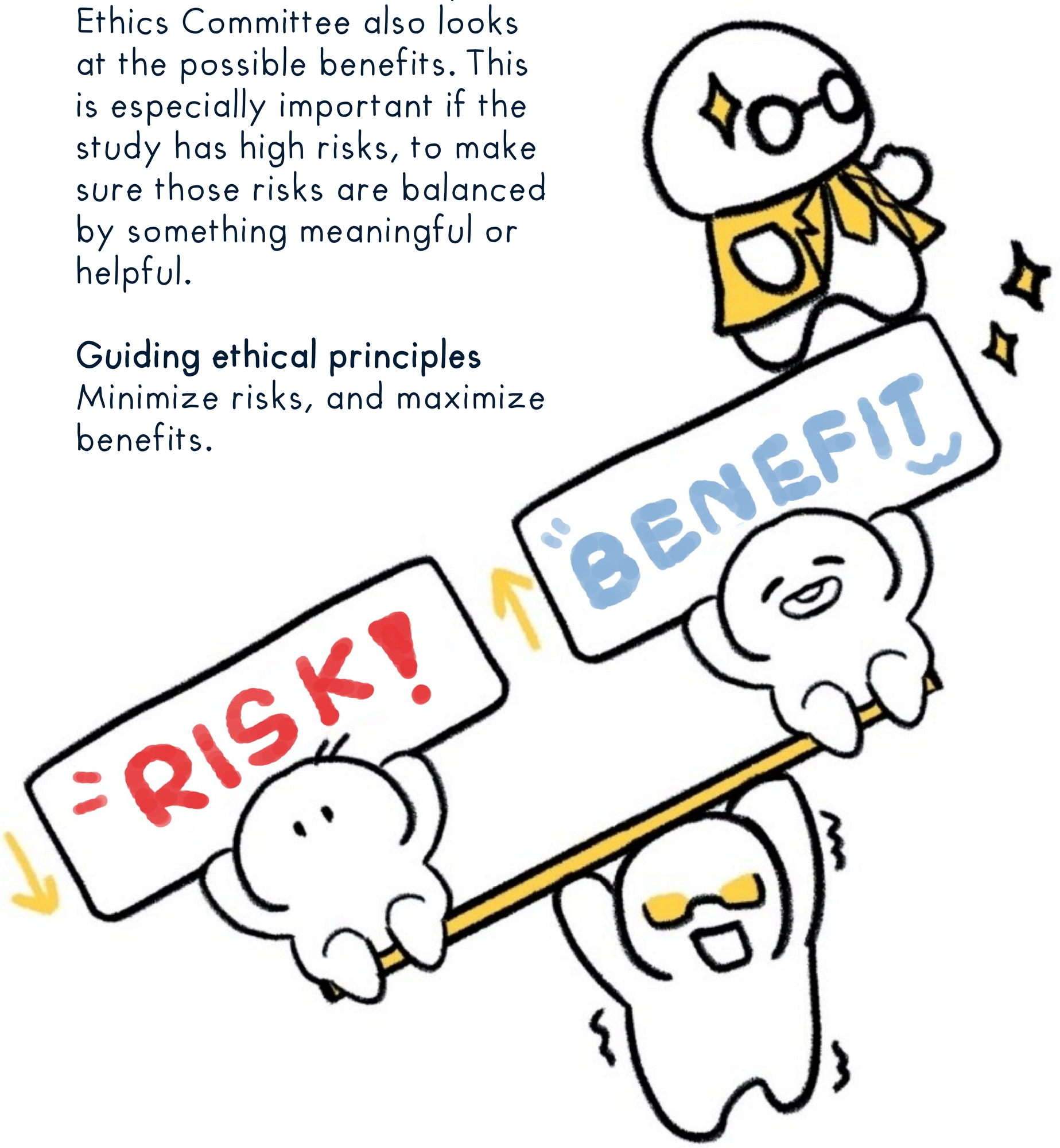
The risk must come only from being part of the research study. It should not include risks that the person already faces in their everyday life.

Consideration of risk Level

When deciding how to handle and keep track of risks in a research study, the Ethics Committee also looks at the possible benefits. This is especially important if the study has high risks, to make sure those risks are balanced by something meaningful or helpful.

Guiding ethical principles

Minimize risks, and maximize benefits.



Example of a risk assessment

Risk categories	Example
No more than minimal risk	• Interview or questionnaire on non-sensitive topics • Finger-prick blood test
More than minimal risk but the research offers direct benefits to the research participants	• Drug testing in research participants or patients with specific diseases
More than minimal risk. There is no direct benefit to the research participant, but the study may contribute to knowledge about the disease or condition affecting them	• Genetic studies using blood samples • New drug trials in healthy participants to identify side effects • Victimization assessment tests

When a research study has some risks, the Ethics Committee also looks at the possible benefits. If the risks are high, the study must offer something important or useful in return. This helps make sure the study is worth doing and keeps people as safe as possible. After learning about the research project and reviewing the participant information sheet, the public representative is invited to share their thoughts and consider the following...

- Is the information provided complete and sufficient?
- Are the details of the research design, procedures, and participant group allocation easy to understand?
- Are the participant roles, research procedures, risk categorization, and participant rights clearly explained and easy to understand?
- Is the informed consent process appropriate?
- Are the guidelines for care and follow-up during and after the research project understandable?
- Are the measures for maintaining participant confidentiality and privacy appropriate?

Guidelines for risk minimization

Appropriateness of the research design and implementation, including how participants are grouped and assigned within the study

- The layperson can write their comments in this section by first getting help from experts and then putting the information into simpler words, like those used in the participant information sheet.
- The layperson must make sure that the information is clear and easy to understand for an average person who might want to take part in the research.

Basic information on the safety of the test product or device

The layperson's comments should show what most people would expect to know about safety before deciding to join a research project. To help with this, think about the following questions:

- Will the participant be fully informed?
- Will the participant receive enough information to understand any risks related to the test product or device?
- To what extent is the participant likely to understand what is being tested?

Appropriateness of the research participants and sample size

- The layperson can help check if the information given to participants during the consent process is clear and easy to understand.
- The layperson should not suggest changes to who can join the research based on medical details, especially if the study involves patients in clinical research. These decisions should be left to medical experts.

Guidelines for risk minimization

Provisions for the care and monitoring of research participants throughout the study, including care in the event of research-related injury

- The layperson can help by thinking about this part of the research from the participants' point of view. They should check if the information is easy to understand, if the steps are clearly explained, and if participants might have any questions or concerns about what is being provided.

Protecting research participants' confidentiality and privacy

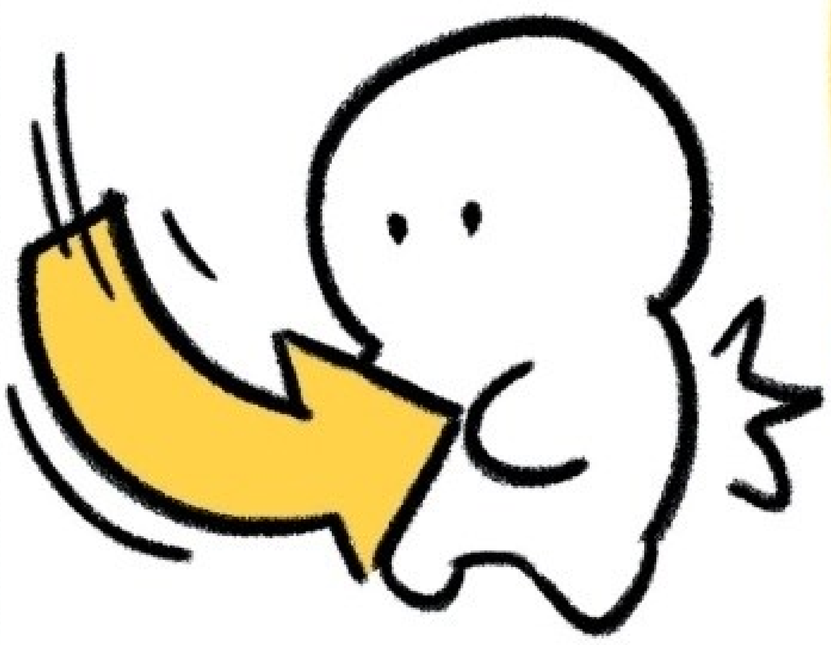
- The layperson should think about whether the way researchers plan to reach out to people is respectful and does not make anyone feel uncomfortable or like their privacy is being invaded. They should also check if the process for asking people to join the study is clearly explained and fair.

Ensuring that the research participants are informed, understand the information, and voluntarily decide to take part in the research project

- The layperson makes sure that people joining the study get enough information to understand any possible risks. They should also be told that they have the right to leave the study at any time, for any reason. If someone feels uneasy or thinks they might be at risk, they can say no or stop taking part, even if the study has already started.

Assessing the potential benefits of the research

Direct benefits



Some research studies may offer direct benefits to participants, such as feeling better from a test drug or learning how to take better care of themselves through training. However, not all studies provide personal benefits. For example, if a study only involves answering questions or doing interviews, participants might not get any direct benefit.

Indirect benefits

Gaining new knowledge, innovations, or treatments

05

Informed consent process

Before deciding whether to join or say no to a research study, people must be given clear and complete information. This helps them make their own decision with confidence and understanding.

Researchers must respect every person who takes part in a study. This means letting people make their own choices and giving extra protection to those who may not fully understand or decide for themselves. To do this, researchers must clearly and kindly explain the study and ask for permission in a careful and respectful way.

The ethics committee checks and approves the consent form that researchers use. Layperson members play an important role by making sure the words and explanations are clear and easy to understand, so that people can decide if they want to join the research.

Valid consent
requires three essential elements

COMPREHENSION

Research participants must clearly understand all aspects of the study

VOLUNTARINESS

Consent must be truly voluntary

RELEVANT INFORMATION

Information must be complete for participants to make informed decisions

When changes to the informed consent form are made during the course of the research, the IRB/EC must review and approve the revised version before it is used by the researcher.

The ethics committee may also ask researchers to get consent again from people who are still in the study. This gives participants another chance to think about whether they want to keep going or leave the study.

The consent process consists of four elements

1. The person seeking consent

- has been trained in the consent process
- is knowledgeable about the research project, and is capable of explaining it clearly and answering all questions
- must not be someone who depends on the researcher, is very close to them, or has power over them. This helps make sure the decision to take part is truly free and not made out of fear or pressure

2. The timing of the consent request

- should avoid asking someone to join the study when the person is busy, stressed, or anxious, because these feelings can make it hard to think clearly and make a good decision

The consent process consists of four elements

3. The location where consent is requested

- should be private and comfortable, so the person feels safe to ask questions and talk openly about anything personal or general

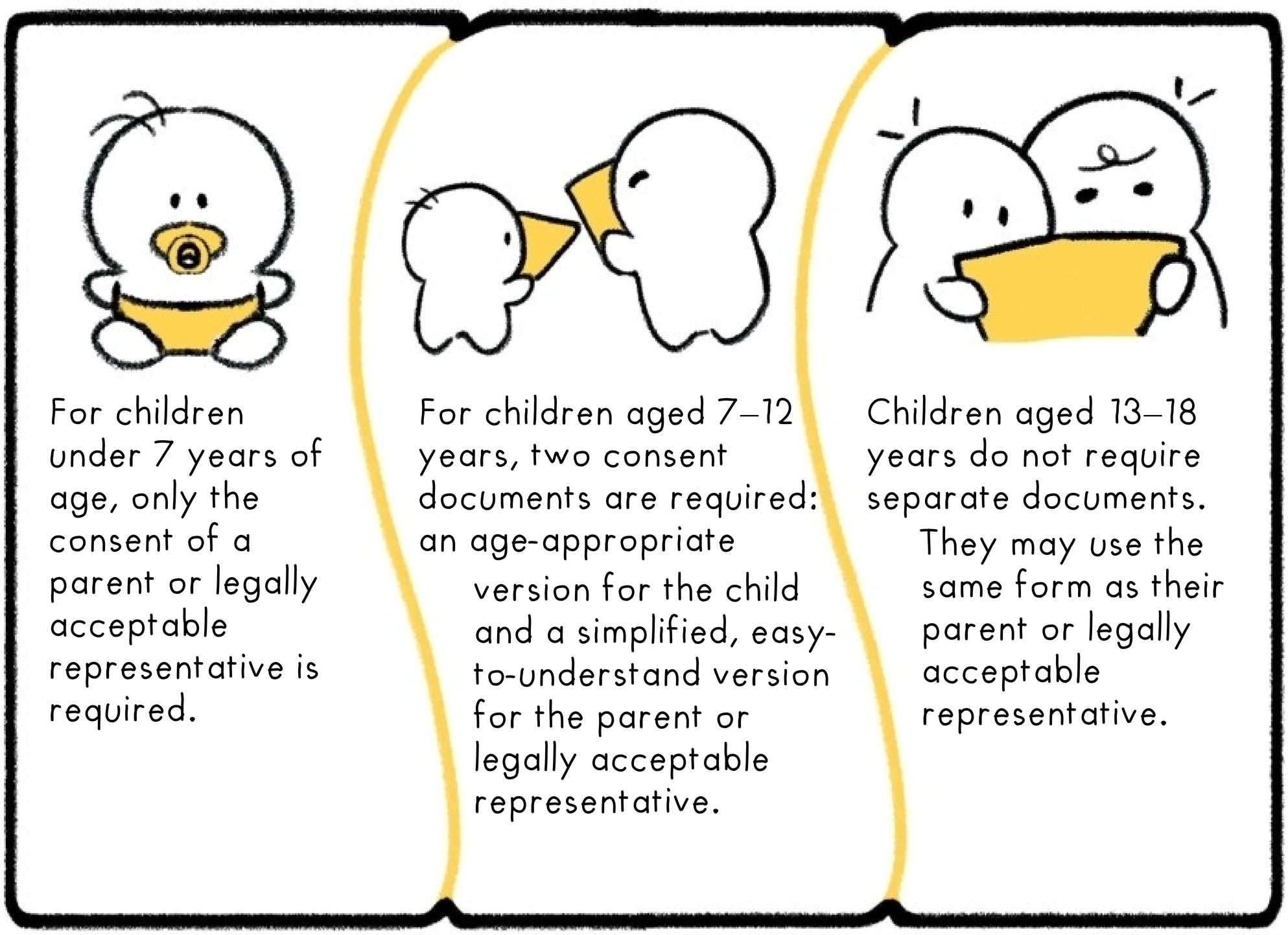
4. Methods of obtaining consent

The IRB/EC reviews the methods used to obtain consent based on the appropriateness of...

- written, verbal, electronic, or implied consent
- explanatory materials such as advertisements, information cards, and audiovisual aides
- enough time to talk, ask questions, and decide whether they want to join the research

When research involves children, both the child and their parent or legal guardian must agree. The child should be part of the decision in a way that fits their age, maturity, and understanding. If a child says no, that choice must be respected, and they should not take part—unless the treatment could directly help their health or the ethics committee decides the child cannot make the decision for themselves.

The consent process does not happen just once—it continues throughout the entire study. Participants can change their minds and leave the study at any time. If a child in the study turns 18 while still taking part, they must be asked to give their own consent again as an adult.



For children under 7 years of age, only the consent of a parent or legally acceptable representative is required.

For children aged 7–12 years, two consent documents are required: an age-appropriate version for the child and a simplified, easy-to-understand version for the parent or legally acceptable representative.

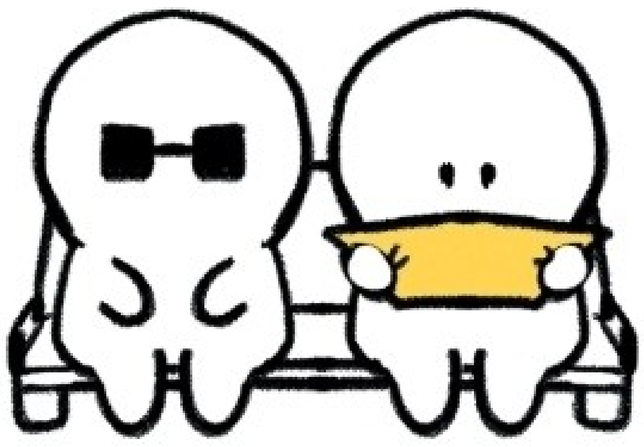
Children aged 13–18 years do not require separate documents. They may use the same form as their parent or legally acceptable representative.

Persons who can provide consent for research involving children

Research type	45 CFR 46 2018	CIOMS 2016
1. Research with no more than minimal risk	One parent (father or mother)	At least one parent
2. Research involving more than minimal risk, or low risk with direct benefits to the participants	One parent (father or mother)	At least one parent
3. Research involving more than minimal risk, or low risk with no direct benefit to the participants, but is likely to contribute to generalizable knowledge	Both parents	At least one parent

Parental consent may sometimes be waived in cases where: (1) the minor has reached the legal age of adulthood; (2) the research involves sexual beliefs and behaviors or drug use; (3) the research involves domestic violence, sexually transmitted infections, pregnancy, abortion, or child abuse; or (4) there is a risk that the parent may question, threaten, or physically harm the participants.

For adults with limited decision-making capacity, researchers should obtain the individual's assent along with the consent of a legally authorized representative.



If the person is illiterate, unable to write, or blind and cannot read the research information sheet, an impartial witness must be present during the consent process.

In research with pregnant women, the woman can give consent by herself if the study helps her, helps both her and the fetus, or has very low risk and adds to useful knowledge.

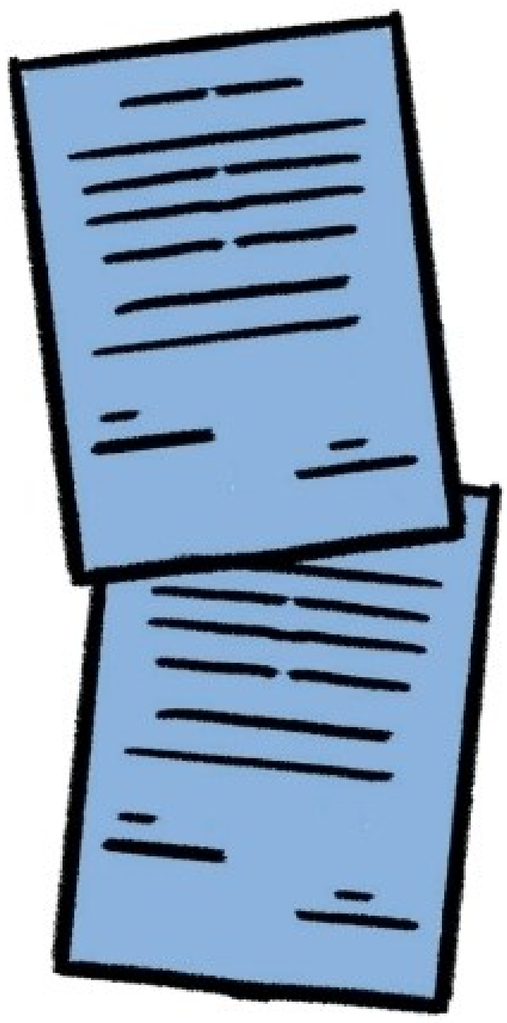
If the research benefits only the fetus, consent should be obtained from both parents—unless the father is unknown—or from the mother alone, with the father consulted as per institutional policy.

Exceptions in the consent process

The IRB/EC may consider waiving the requirement for informed consent if

- the research has social value,
- the research poses no more than minimal risk
- obtaining consent is impracticable
- appropriate data protection measures are in place

The IRB/EC may consider waiving the requirement to sign the consent form if doing so would increase risk or danger to the participant.



The IRB/EC may allow enrollment before signing an emergency consent form, provided consent is obtained as soon as possible from the participant or their legal representative.

Ethics committees may consider approving the use of deception in the informed consent process if

- the research poses no more than minimal risk
- the deception or omission of information is necessary to obtain valid data
- participants are fully debriefed and given accurate information at the end of the study

Review of the informed consent form

1. Review the consent process to ensure that participation is voluntary
   - appropriateness of the person obtaining consent, timing, location, and method

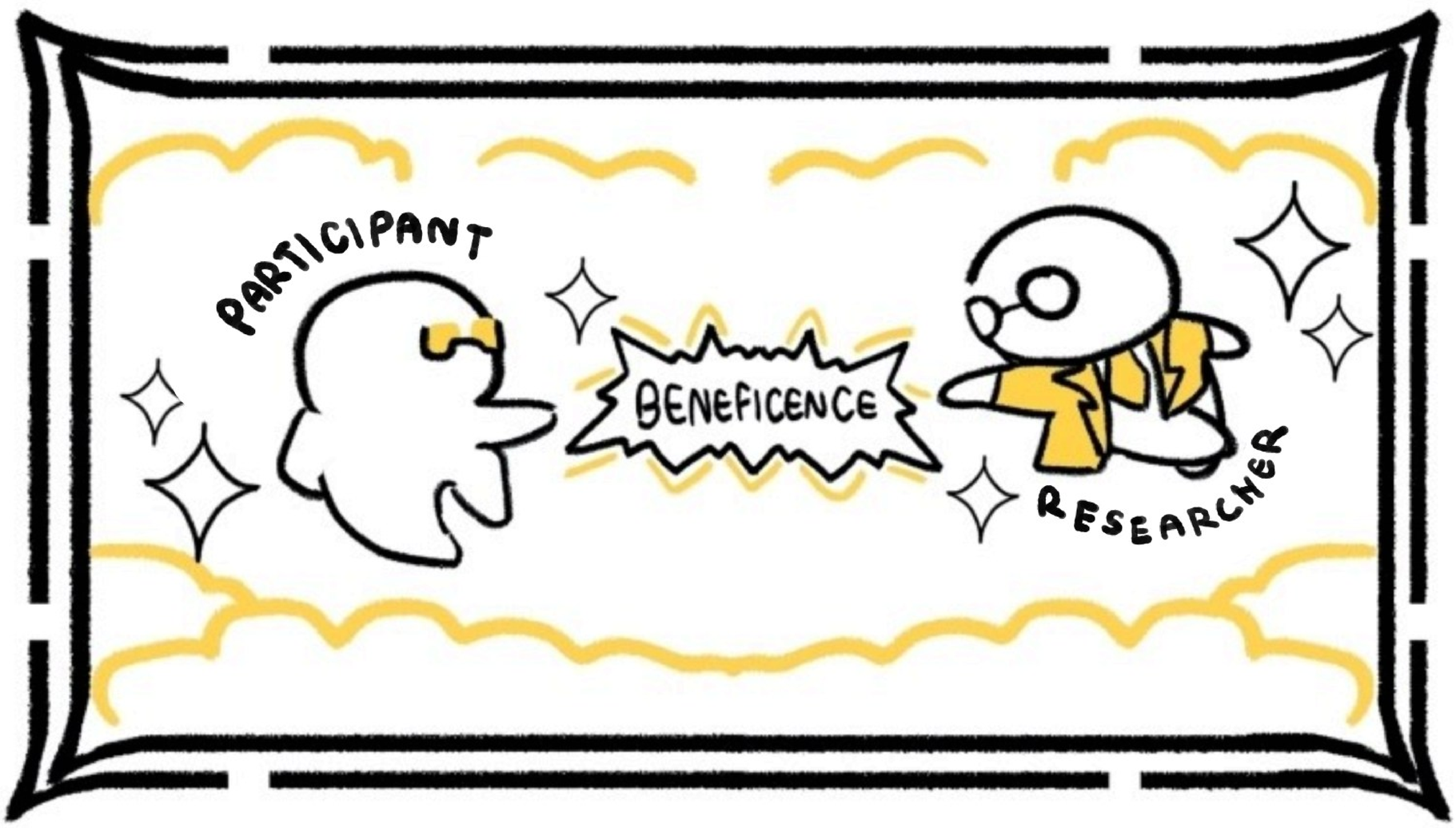
2. Review the completeness of information in accordance with international standards
   - states that the activity is research
   - states that participation is voluntary
   - provides clear research information
   - identifies risks and benefits from the research
   - specifies compensation
   - specifies confidentiality and its limits
   - specifies alternatives to participation

3. Review the appropriateness of the language used for research participants
   - concise and easy to understand
   - free of prohibitive or overly persuasive language
   - free of coercive language
   - avoids technical jargon
   - avoids language that may cause psychological harm

4. Final check that the informed consent form includes all three essential elements (valid consent)
   - contains sufficient information for decision-making (relevant information)
   - uses language that promotes understanding and contains no harmful language (comprehension)
   - is free from coercive, pressuring, or overly persuasive language, and the consent process does not diminish the participant's free will (voluntariness)

06

Risk of breach of privacy and confidentiality

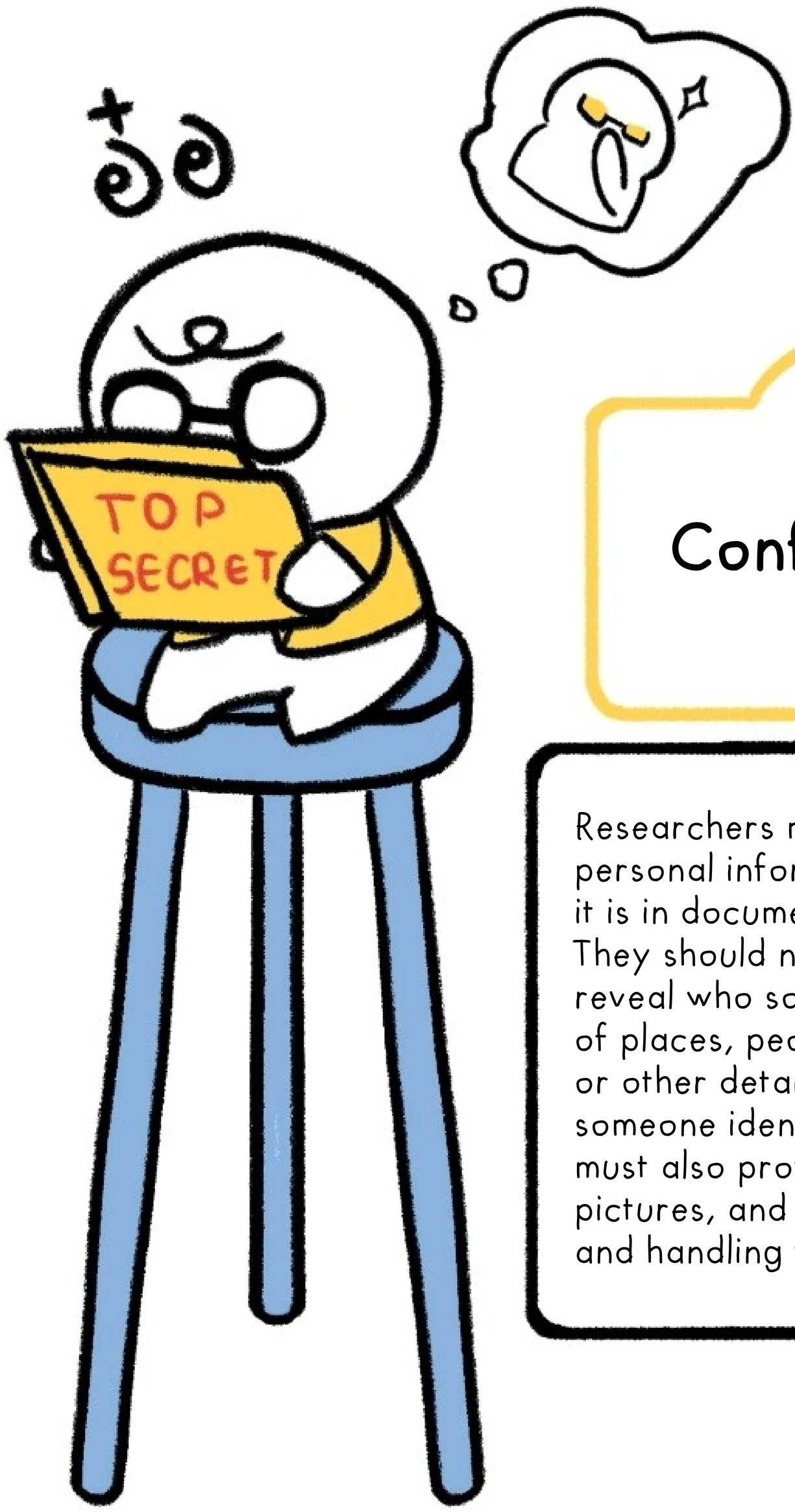


Protecting privacy and keeping information confidential is part of doing good and avoiding harm. Researchers must look at possible risks and do their best to reduce them. People's right to privacy must always be respected.

Researchers must respect participants' privacy and prevent the disclosure of personal information, particularly data that could lead to their identification.

Privacy

Researchers and anyone helping with the study must respect the privacy and rights of participants. They should not, for example, talk about or invite someone to join a sensitive study in a public place, visit their home in a way that could reveal they are part of the study, or use information from a database without permission.



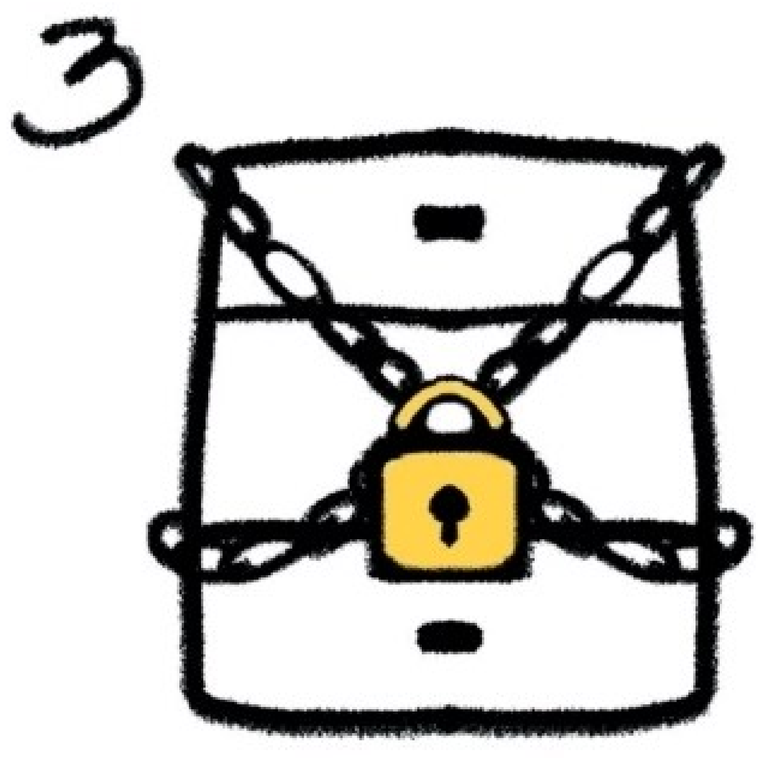
Confidentiality

Researchers must keep participants' personal information private, whether it is in documents or other materials. They should not publish results that reveal who someone is, such as names of places, people who gave the data, or other details that could make someone identifiable. Researchers must also protect all information, pictures, and recordings by storing and handling them safely.

Where in the research should potential breaches of privacy and confidentiality be identified?

Details of data collection

Details of permission received from officials or authorized persons to provide information



Details of the research methodology and informed consent form, specifying the type of data to be collected, where it will be stored, for how long, and when it will be destroyed

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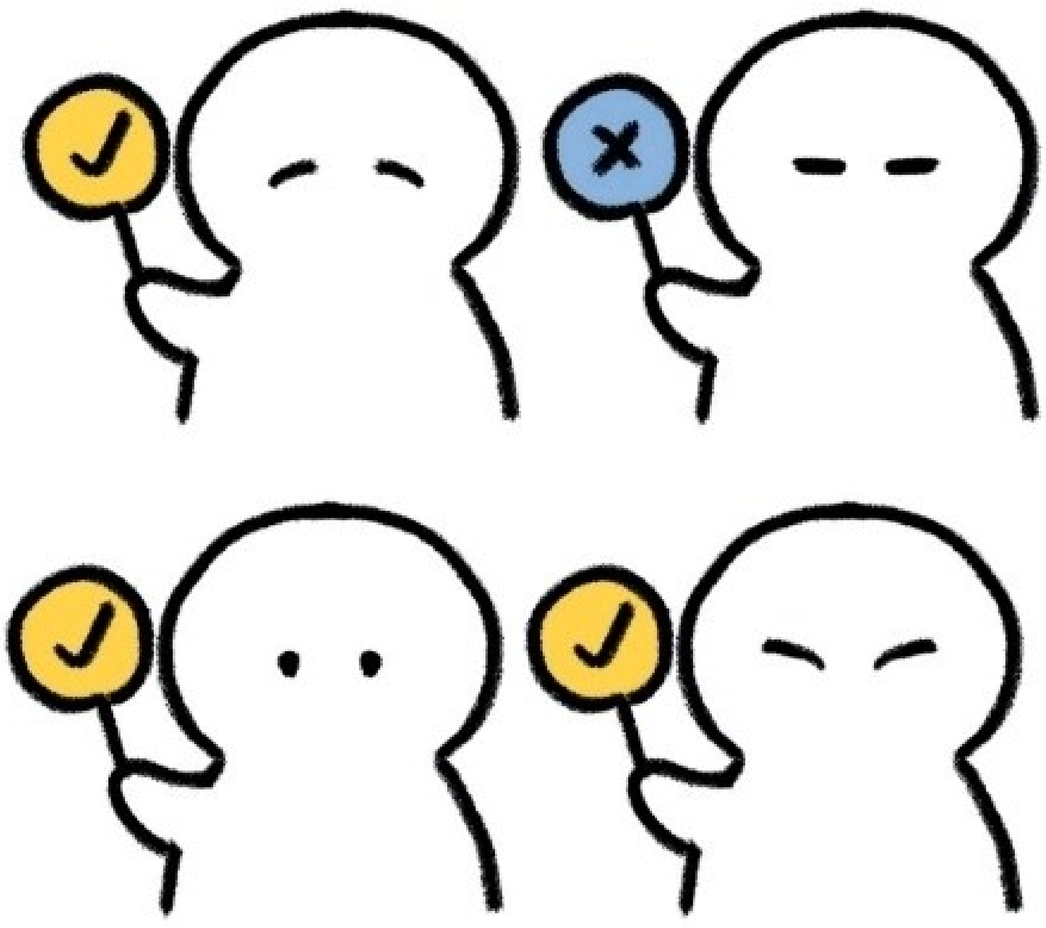


Selection of research participants

Choosing who can join a research study must follow the idea of fairness.

The good and bad parts of the study should be shared equally. No group should be left out of the benefits or asked to take on more of the risks than others.

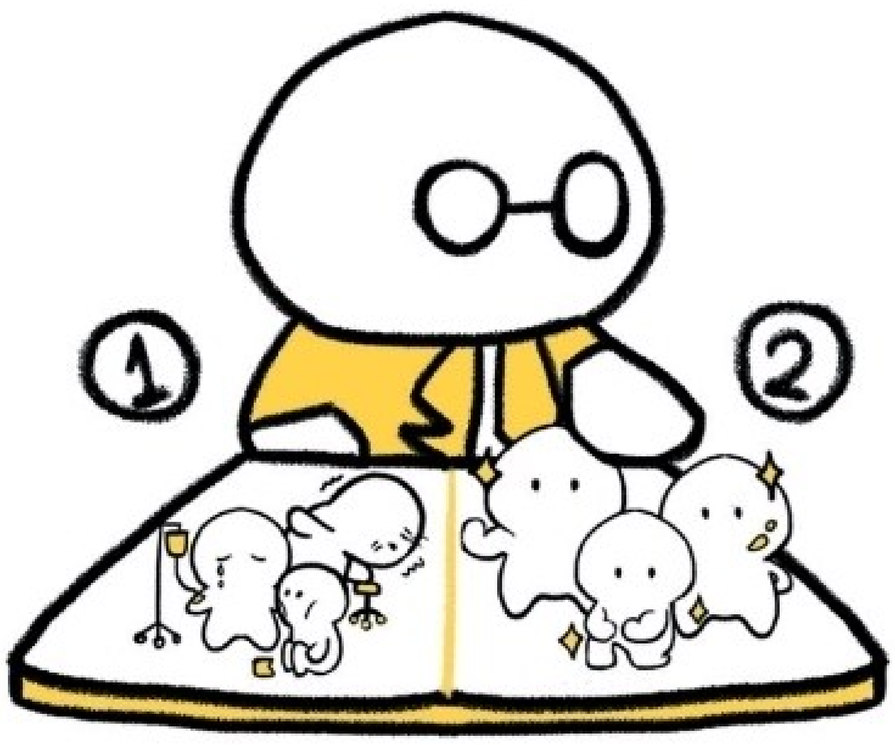
Vulnerable groups
These groups should not be included in research solely for reasons of convenience, ease of persuasion, or because they are more likely to compromise.

Research problems
Should be directly related to the group involved, so that the research benefits that group

People who may benefit from the research should not be excluded or discriminated against
Those living in poverty or with chronic illnesses should have the opportunity to participate.

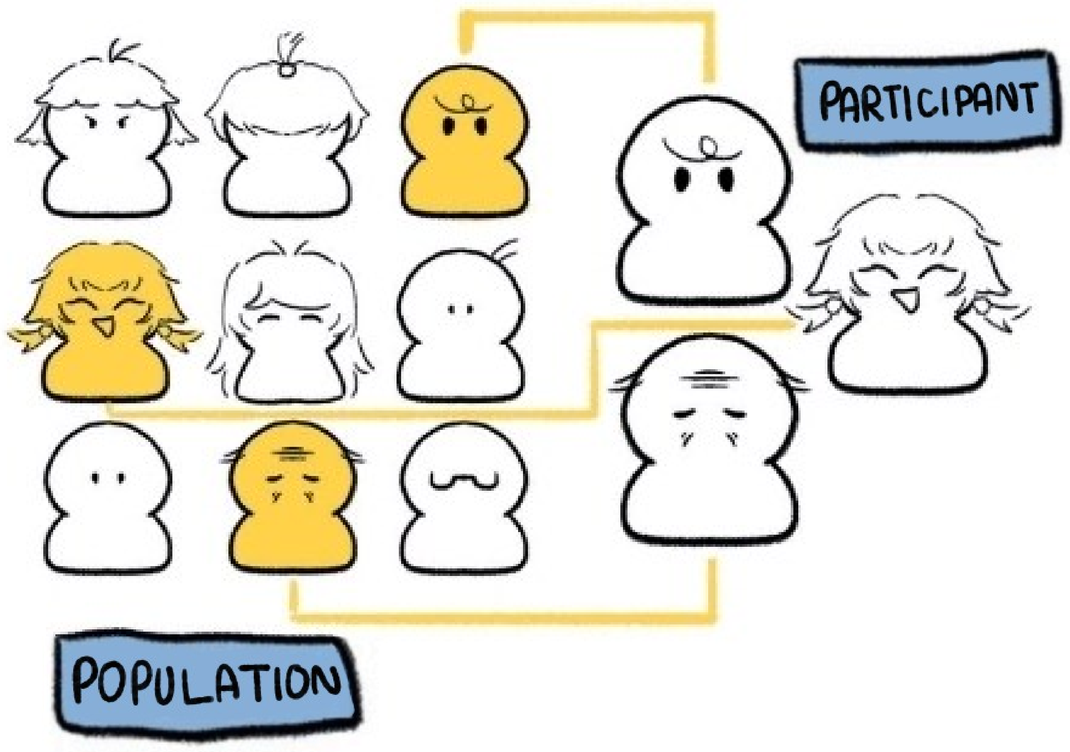
Researchers should not pursue benefits from research without considering the participants
Beyond academic advancement or funding, research must also benefit the participants.

Where in the research process should fairness be evaluated?



If the research has risks and there is no available cure, it should first involve people or groups who are less affected—unless the study focuses on a disease that mostly affects those at higher risk or with more serious illness.

The way communities are chosen to take part in the research should be clearly explained. It should say whether all communities will have the same chance to join or if they will be picked randomly.



Health Systems Research Institute (HSRI)
Ministry of Public Health, Thailand

KEY HIGHLIGHTS FOR LAYPERSONS

The Key to Success for Laypersons on Research Ethics Committees/ Institutional Review Boards