

The importance of informed consent in collaborating with stakeholders





How it works

This module is presented as an interactive PDF, providing you with a seamless navigation experience. You can easily move to different topics by simply clicking on them. In addition to the visible navigation buttons on the side of each page, you will also find clickable sections within the module. These clickable sections are identified within the text.



page in a chapter

You also have the option to view this PDF in a continuous scrolling mode if you prefer.





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LEARNING OBJECTIVES

After completing this module, you can:

- Explain the significance of utilizing informed consent when collaborating with stakeholders.
 - 2 Describe the process of writing an informed consent.
 - Write an informed consent form for your project.



1. WHAT IS INFORMED CONSENT?





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WHAT IS INFORMED CONSENT?

Informed consent is an ethical practice in research that ensures that individuals participate voluntarily, fully understanding the purpose, procedures, potential benefits, and risks of the project.

This knowledge allows participants to make a **voluntary**, **informed decision about their participation**.





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WHAT IS INFORMED CONSENT?

There are **four key elements** when it comes to obtaining informed consent:

- 1. Participation must be voluntary.
- 2. Participants must be legally competent.
- 3. All relevant information should be provided.
- 4. It should be ensured that participants fully understand the provided information.

These four elements form the foundation of a robust informed consent process in stakeholder collaborations.



2. WHY IS INFORMED CONSENT IMPORTANT?



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WHY IS INFORMED CONSENT IMPORTANT?

There are three main reasons why informed consent is essential:







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WHY IS INFORMED CONSENT IMPORTANT?

There are three main reasons why informed consent is essential:

Protects participants' rights

Informed consent ensures that participants fully understand their involvement, safeguarding their autonomy and personal rights throughout the research process.

See less

Promotes ethical research practices

Learn more



Builds trust and transparency

Learn more





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WHY IS INFORMED CONSENT IMPORTANT?

There are three main reasons why informed consent is essential:

Protects participants' rights

Learn more



Promotes ethical research practices

Using informed consent aligns with researchers' ethical obligations to treat participants with fairness and integrity, in accordance with international standards and agreements.

See less

Builds trust and transparency

Learn more





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WHY IS INFORMED CONSENT IMPORTANT?

There are three main reasons why informed consent is essential:

Protects participants' rights

Learn more



Promotes ethical research practices

<u>Learn more</u>



Builds trust and transparency

Informed consent fosters a trustworthy relationship between researchers and participants, ensuring transparency and mutual respect in the research process.

See less



3. HOW TO GET INFORMED CONSENT?



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HOW TO GET INFORMED CONSENT?



When getting informed consent, it is crucial to determine who can or cannot consent.

Any competent individual who comprehends the information and has the capacity to refuse, can provide consent.

However, there are individuals who may not be able to provide consent due to incapacity, lack of understanding, or restricted freedom.



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These individuals include:

- Minors or children, who are not legally able to give consent.
- Adults with cognitive impairments, who may not fully comprehend the information.
- Adults in situations of restricted freedom, such as prisoners or refugees in camps, whose ability to make independent decisions may be compromised by power imbalances, language barriers, or psychological distress.



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In these cases, a parent or legal representative may provide consent on their behalf. However, the primary participant (child or patient) should also receive information tailored to their level of understanding, enabling them to comprehend, as much as possible, what they would be agreeing to.



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HOW TO GET INFORMED CONSENT?

Informed consent must always be active, meaning participants must not only be fully informed about the project but also take a deliberate action to indicate their agreement to the proposed terms for participation.





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HOW TO GET INFORMED CONSENT?

The most common method for obtaining informed consent is by having participants sign a document that outlines all relevant information and conditions of the project (an informed consent form).





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HOW TO GET INFORMED CONSENT?

The most common method for obtaining informed consent is by having participants sign a document that outlines all relevant information and conditions of the project (an informed consent form).

While this has traditionally been done with pen and paper, it's now increasingly common to **obtain digital consent**, either through a digital signature or by checking a box in an online questionnaire. A recorded oral agreement is also possible in some cases.





4. HOW TO DRAFT AN INFORMED CONSENT FORM?



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- Give participants a clear explanation of the aims, overall purpose, methods and implications of the research.
- 2 Explain that participation is voluntary



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- Give participants a clear explanation of the aims, overall purpose methods and implications of the research.
 - 2 Explain that participation is voluntary.
- Remind participants that they have a right to withdraw their consent a any time without any consequences.



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- 2 Explain that participation is voluntary
 - Remind participants that they have a right to withdraw their consent at any time without any consequences.
- Explain the degree of benefit, risks, burden or discomfort involved in participation. Give an estimate of the time and effort expected of participants.



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- Remind participants that they have a right to withdraw their consent at any time without any consequences.
 - Explain the degree of benefit, risks, burden or discomfort involved in participation. Give an estimate of the time and effort expected of participants.
- Explain precautions to ensure participants' safety and provide information on insurance, if there is any.



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- Explain the degree of benefit, risks, burden or discomfort involved in participation. Give an estimate of the time and effort expected of participants. EUR: Potential Risks and Discomforts
 - Explain precautions to ensure participants' safety and provide information on insurance, if there is any.
- Explain who is funding the research and for what purpose



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- Explain precautions to ensure participants' safety and provide information on insurance, if there is any.
 - Explain who is funding the research and for what purpose.
- Disclose who will benefit from the research



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- Explain who is funding the research and for what purpose
 - Disclose who will benefit from the research.
- Give a firm commitment to protecting respondents' anonymity and privacy (provided that this can genuinely be guaranteed).



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- **7** Disclose who will benefit from the research
 - Give a firm commitment to protecting respondents' anonymity and privacy (provided that this can genuinely be guaranteed).
- Make a clear commitment to treating personal and sensitive information confidentially.



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- Give a firm commitment to protecting respondents' anonymity and privacy (provided that this can genuinely be guaranteed).
 - Make a clear commitment to treating personal and sensitive information confidentially.
- Reassure participants that there are security procedure for analyzing any data gathered.



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- Make a clear commitment to treating personal and sensitive information confidentially.
- Reassure participants that there are security procedures for analyzing any data gathered.
- Explain clearly who will have access to any data that participants provide.



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- Reassure participants that there are security procedures for analyzing any data gathered.
 - Explain clearly who will have access to any data that participants provide.
- Consider any unintended/unexpected/incidental findings and explain how you intend to deal with such findings.



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- Explain clearly who will have access to any data that participant provide.
 - Consider any unintended/unexpected/incidental findings and explain how you intend to deal with such findings.
- Explain briefly where research findings will be published



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- Consider any unintended/unexpected/incidental findings and explain how you intend to deal with such findings.
 - 13 Explain briefly where research findings will be published.
- Offer to provide respondents with further information about research if they ask for it.



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- Explain briefly where research findings will be published
 - Offer to provide respondents with further information about research if they ask for it.
- Give the name and contact details of the contact person who can answer any queries participants may have.



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- Offer to provide respondents with further information about research if they ask for it.
 - Give the name and contact details of the contact person who can answer any queries participants may have.
- Clarify possible uses to which data may be put in future (if this is envisaged) and clarify whether participants will be asked for consent again if this is the case. Cover any issues relating to the copyright of data and other materials used in the research



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- Give the name and contact details of the contact person who car answer any queries participants may have.
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Elements to include

Find the full list of elements here:



Click to open



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Templates

For a convenient format of informed consent that addresses all the essential elements, you can access templates in both Dutch and English on Erasmus University's website, that makes sure you do not forget anything important.





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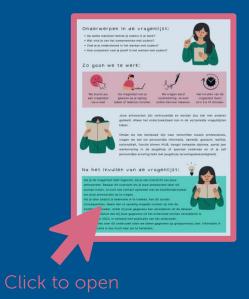
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Examples

Click to find examples of informed consent forms (in Dutch).







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Checklist for participants

As part of the informed consent process, you can use the following questions to ensure that your participants are fully informed and understand what they are agreeing to:



1. Do you know why we are asking you to take part in this study? Do you know what the study is about?





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Checklist for participants

As part of the informed consent process, you can use the following questions to ensure that your participants are fully informed and understand what they are agreeing to:



2. If you decide not to take part in this research study, do you know what your options are? Do you know that you do not have to take part in this research study if you do not wish to?

Do you have any questions?





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3. If you decide to take part in the study, do you know how much time will the interview take? Where will it take place? Do you know that we will be sending you transport to pick you up from your home? Do you know how much time will the discussion with other people take? If you agree to take part, do you know if you can stop participating? Do you know that you may not respond to the questions that you do not wish to respond to? Etc. Do you have any more questions?





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As part of the informed consent process, you can use the following questions to ensure that your participants are fully informed and understand what they are agreeing to:



4. Can you tell me if you have understood correctly the benefits that you will have if you take part in the study? Do you know if the study will pay for your travel costs and time lost, and do you know how much you will be reimbursed? Do you have any other questions?







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Checklist for participants

As part of the informed consent process, you can use the following questions to ensure that your participants are fully informed and understand what they are agreeing to:



5. Do you know that you do not have to take part in this study if you do not wish to? You can say no if you wish to? Do you know that you can ask me questions later if you wish to? Do you know that I have given the contact details of the person who can give you more information about the study?



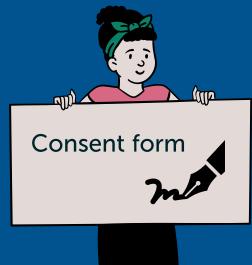
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5. FINAL STEPS



Literature

References

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- https://www.eur.nl/en/research/researchservices/research-quality-integrity/ethicalreview/informed-consent







About this e-module

AUTHORS

The content of this module was developed by **Dr. Crystal Smit** Assistant Professor (project lead) and **Denise Levy**, learning innovator, both from the Erasmus University Rotterdam

CONTEXT

This e-module is intended to be used in impactdriven courses where students collaborate with external stakeholders such as non-profit organizations, municipalities, health institutions, youth initiatives, schools, and others.

DESIGN

The instructional design of this e-module was developed by Akke van der Laan, Learning & Development Expert at L&D talents. The graphic design is done by <u>Risbo</u>.

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Impact at the Core

