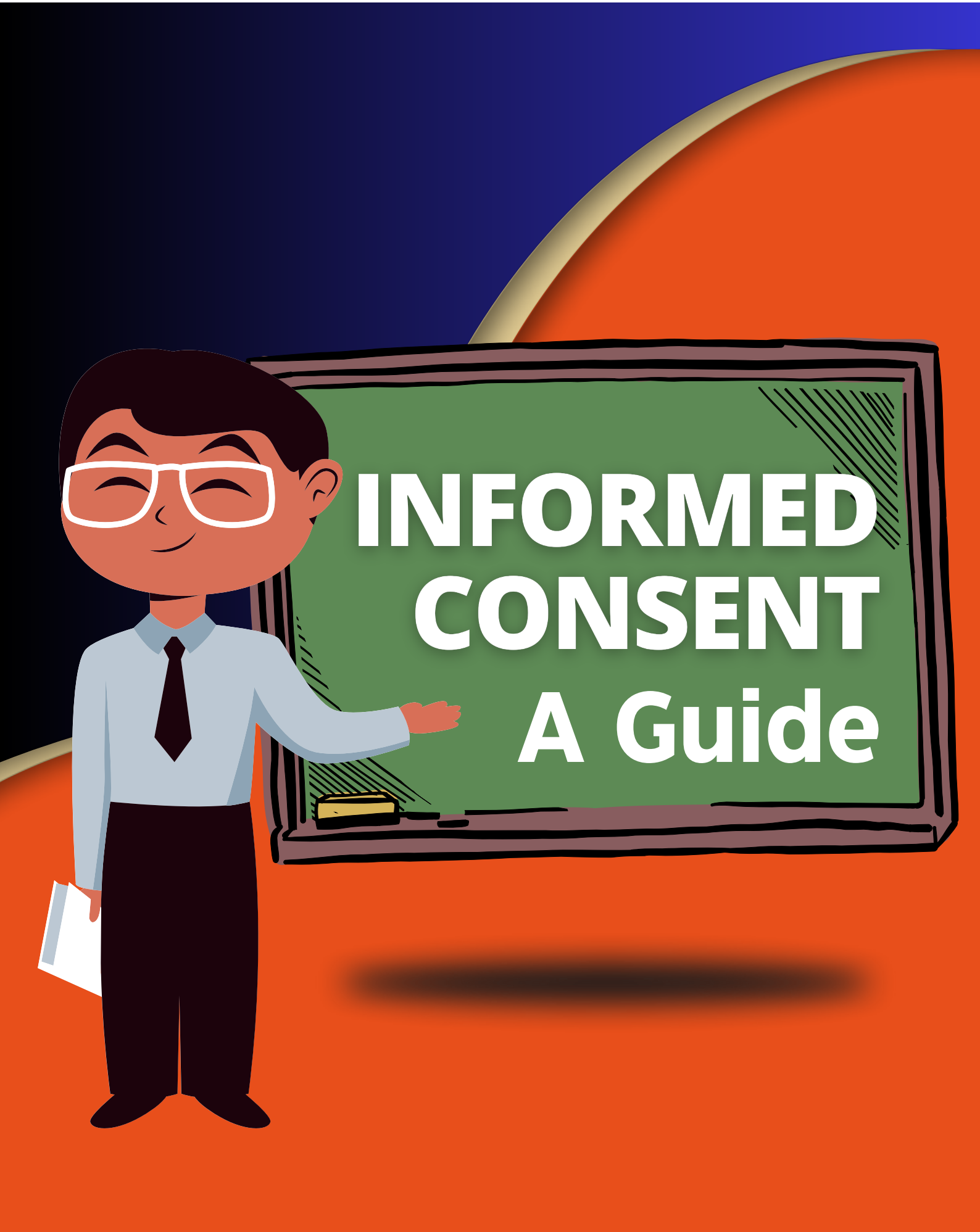
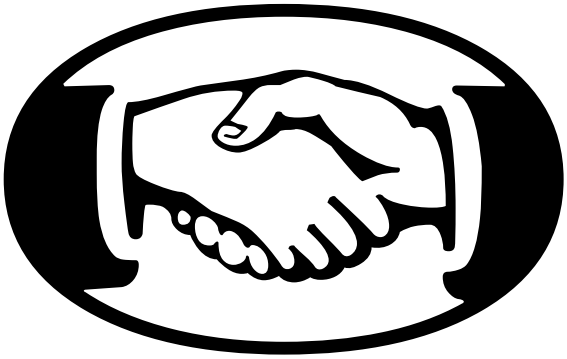
NEARVET

Co-funded by the European Union



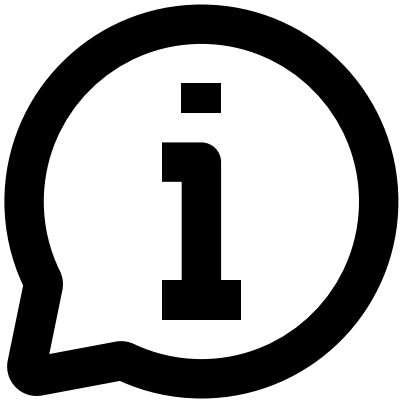
What is Informed Consent?

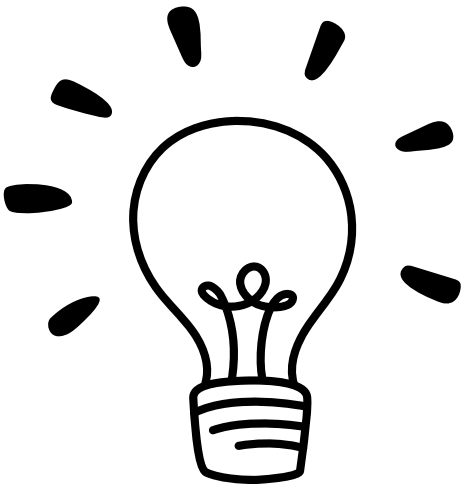
Informed Consent entails that a person:



Voluntarily agrees to participate in a research study;

After having been informed about all the aspects of the study;





And, hence, having a full understanding of what their participation entails, including the associated risks and benefits of participating.

What is Informed Consent?

Informed consent is not merely about obtaining a subject's signature on a consent form. It involves giving the potential subject sufficient information, ensuring they understand it, allowing ample time for questions, and continuously providing information as the survey progresses.

Obtaining Informed Consent: Challenges in the process

1

- **Informed consent forms sometimes include excessive amount of detail, often written at a reading level beyond the capacity of most of the potential participants.**

- If the consent process is not communicated in a way easily understood by potential participants, it can lead to confusion and hinder understanding, ultimately discouraging participation.

Obtaining Informed Consent: Challenges in the process

2

- **“The obtaining consent process is often treated as a “one-size fits all””.**

- This is not true. There are different types of surveys, for example those with low participation risk, that may not require written consent. However, this does not mean that an explanation of the study, including its purpose and the potential risks and benefits is not required.

Obtaining Informed Consent: Challenges in the process

3

- **A common misconception is that you have to “sell” the study to potential participants in order to convince them to participate by signing the consent form.**

- Informed consent is not a sales practice. The aim is to provide participants with the information they need in an understandable way, in order to be able to make informed decisions about study participation.

Obtaining Informed Consent

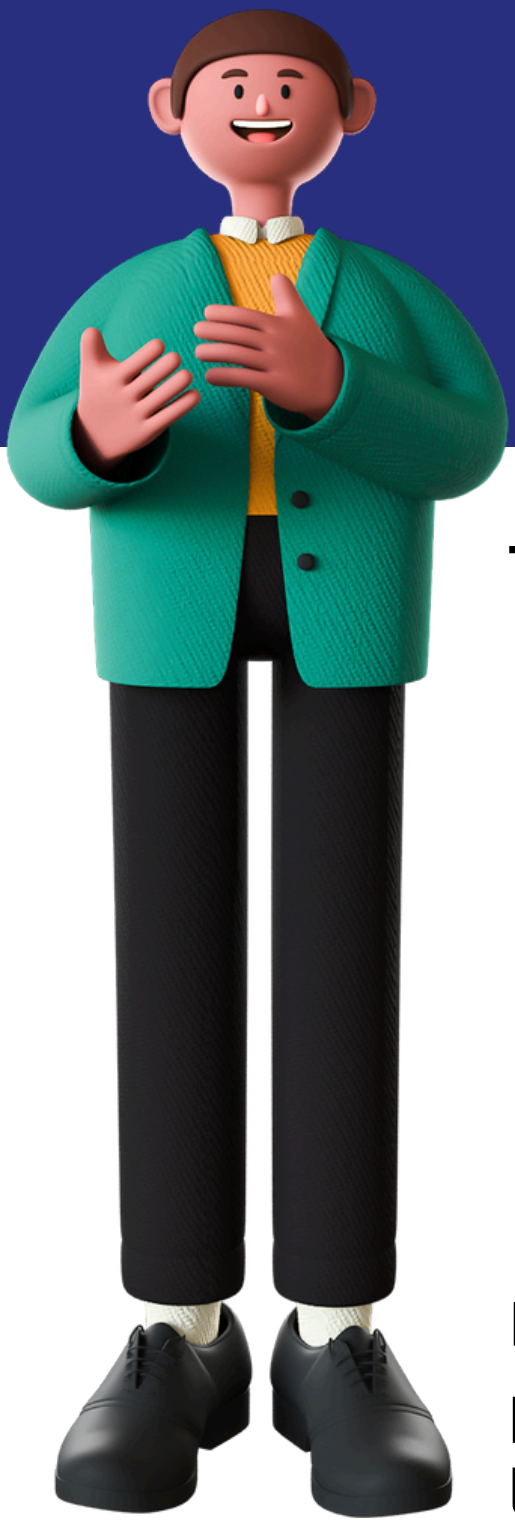
It has been shown that participants who understood their role in the research were more likely to complete the study. Therefore, effective informed consent reduces the likelihood of participant withdrawal.

Effective Informed Consent: Tips for the Researcher

Be well-prepared to explain the study to potential participants:

- **Read the study materials carefully.**
- **Understand the details.**
- **Ask your self questions such as whether you understand the study objective and the design to achieve the objective.**

Effective Informed Consent: Tips for the Researcher



Develop an introductory verbal script to help yourself to better approach potential participants.

The script must include:

- **Who you are.**
- **How did you get the permission to approach the participant.**
- **What's the purpose of the survey you are conducting.**

Before proceeding further, ask participants if they want to learn more about the research.

Informed Consent : The Procedure

Informed Consent is not synonymous with simply obtaining a subject's signature on the consent form. Informed consent involves providing a potential subject with adequate information, facilitating comprehension of that information, providing the opportunity for questions from the subject, and continuing to provide them information as the research process progresses. Informed consent includes an education and information exchange that takes place between the researcher and the potential subject.

Steps

Step 1

The researcher must explain the study to the potential subject verbally, providing all the necessary information: purpose, procedures, risks, benefits, alternatives to participation etc. The potential subject must be free to ask as many questions as they want.

Informed Consent : The Procedure

Step 2
Following the verbal explanation, the researcher must provide a written consent form, allowing sufficient time for the potential subject to decide whether to participate in the research or not. “Sufficient time” can vary from hours to days, depending on how long it reasonably takes to evaluate the procedures, risks, potential benefits, and alternative treatments.

Step 3
After allowing the potential sufficient time to read the consent form, the researcher - who must be listed namely on the consent form - should meet the potential subject and answer any additional questions they may have, concerning the survey.

Step 4
The researcher may obtain a written agreement from the subject to participate in the research at that time.

Assessing Subject Comprehension

Assessing subject comprehension of the research, including the risks and benefits involved, is a critical component of the consent process. Ensuring that the potential subject understands the research is solely researcher's responsibility. Hence, it is important the researcher not only to response to questions but also pose questions. Asking questions can further the discussion, elicit questions from the potential subject, prompt the potential subject to think more carefully about the study and help the researcher decide whether the person has indeed understood the study.

Questions to be effective must be open-ended and non-directive. The researcher must ask for explanation rather than yes or no answers, because this kind of questions can be answered in a variety of ways, and do not already contain the correct answer. Open-ended questions are often introduced with "what", "where", "how often", "when" and "please describe".

The researcher must avoid closed-ended questions that tend to bring discussion to a stop. "Do you understand?", "Do you have any questions?", "Do you understand that there are some risks to participating in this research?" are examples of closed-ended questions.

Required Signatures

After the subject has agreed to participate in the study/research must sign and date the consent form. The researcher who has oriented and consented the subject must sign and date the consent form as well. The type of the research may include an impartial witness signing too.
The researcher's signature cannot pre-date the subject's signature. The researcher must provide a copy of the consent form to the subject to be used as a continual reference for items such as scheduling of procedures and for emergency contact information. Unless both the subject and the researcher signs, the subject is not technically enrolled.

The researcher's signature entails that the subject, meeting all study inclusion criteria, was appropriately consented and understands the requirements of the study. It also means that the subject has received a copy of the informed consent document.

Re-consent and Significant New Findings

The consent process does not end by obtaining the signature. Maintaining informed consent requires that subjects will be provided with the new information may arise during the research process and can potentially affect a subject's decision to continue their participation in the study: i.e. changes to the research plan, change in risk/benefit profile, the results of related research etc.

When this, eventually, happens, the researcher must submit an amendment request to revise the consent form and provide a re-consent cover letter that briefly describes what changes have been made since the last provided informed consent. A re-consent memo should be attached at the front of the consent form. The memo should be designed in a way that facilitates the re-consent process by emphasizing the revisions made.

Re-consenting is necessary, when:

- New risks are identified
- An increase in risk is observed
- A decrease in expected benefit is observed
- A change in research procedures occurs