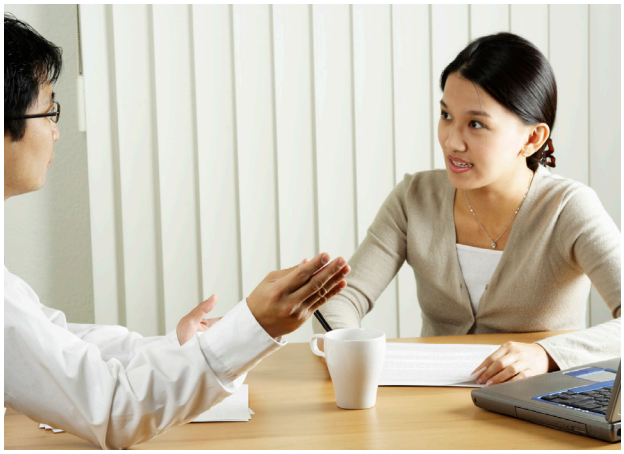
Academy of Nutrition and Dietetics
Dietetics Practice Based Research Network

The Informed Consent Process

What is informed consent?

Informed consent is a process of information exchange about the research including reviewing eligibility or recruitment materials with the subject, reviewing the informed consent document, answering questions, and checking for subject understanding. Usually, but not always, at the end of this process the informed consent is documented via a signature from the subject. One of the main goals of the informed consent process is to help the potential subject make a risk-benefit ratio assessment regarding their study participation.



- Explain eligibility
- Provide relevant information about project goals and requirements
- Assess understanding
- Answer questions
- Obtain consent
- Document (if necessary)

The Informed Consent Document—What are the required elements?

An Informed Consent Document should include all of the following elements:

- Research Statement—be clear that the project is research, also include the purpose, duration, and required procedures
- Risks and discomforts
- Benefits (remember that payment or compensation is not a benefit)
- Alternatives—What are other options to the subject besides taking part in the research (including not taking part in the research as an option)
- Confidentiality and limits thereof (remember that regulatory agencies may look at the records)
- Compensation for study participation
- Contact person
- Voluntary Refusal and Right to withdraw—subject may stop participation at any time and not lose any benefits they are eligible to outside of research

Depending on the type of study, the document may require these additional elements (most people include both lists in all documents to be safe)

- Unknown risks to participants (a statement saying that there may be unknown risks which are not listed)
- Termination to participation (why would a subject be removed from the study by the investigator, for example for noncompliance)
- Costs (does the patient or their insurance have to pay for any of the study treatments, tests, or visits?)
- Consequences of withdrawal (loss of study treatment etc)
- Notification that new findings will be given to participants (in case it changes their willingness to participate)
- Number of participants in the study

In addition, your consent form must:

- Be at a reading level that is understandable to subjects. It should also be in the native language of your participants
- Ensure that there is no undue influence on potential subjects in deciding to participate
- When Protected Health Information is being collected, a statement about HIPAA must be included, either in the same form or on a separate one (per facility policy)

The informed consent document is a tool in the process and a record of the process. It is not a substitute for talking to the subject (except in certain cases where the IRB has approved a modified process, as in the case of a survey).
IRB approved consents should have a stamp or other approval mark on them. Do NOT use an unstamped consent or an expired consent.

Does the consent process always have to be documented?

A waiver of the requirement for documentation of informed consent will be granted by the IRB if:

- The principal risk in the study is a breach of confidentiality and the only link between the participant and the research is the consent document (thus the consent document poses a risk)
- There is minimal risk of harm and none of the procedures require consent outside the context of research participation (for example a telephone or internet survey)

Is the consent process always required?

There are instances when the entire process of informed consent may not be required (waiver of consent).

- Research involves no more than minimal risk to participants
- Waiver will not negatively affect the rights or welfare of subjects
- Research could not be conducted reasonably without a waiver (creating a bias about the study subject, large pre-existing databases)
- Subjects usually still receive an information sheet either at the beginning or conclusion of the research

Remember that the IRB must give these permissions, you cannot decide yourself whether the requirement for consent or documentation can be waived. The goal of the IRB is to protect the rights and welfare of the research subjects, ensure that subjects understand what they are agreeing to and have weighed the risks and benefits to make an informed decision.