

Informed Consent in Sport Science

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Obtaining informed consent is a prerequisite for a subject's participation in a research project. Informed consent is the potential subject's formal agreement to take part in a research project. The process of obtaining consent includes providing subjects with adequate information. Important components of a written informed consent document include plain-language statements about the research design, the risks and benefits of taking part, and the assurance of confidentiality. The informed consent document should be culturally sensitive, make clear the subject's right to withdraw without obligation, and include an invitation to ask questions about the project. Responsibility for obtaining informed consent rests with the researcher.

KEYWORDS: ethics, participants, research, subjects

[Download templates](#) (in rich-text format) for information and consent forms.

What is Informed Consent?

Scientific developments and technological advances have resulted in increased ability to manipulate human subjects. In exercise and sport science, procedures may involve the researcher taking blood samples and biopsies, using radioactive tracers, requiring the subject to exercise to maximum effort, or performing potentially invasive psychological procedures. Past abuses in biomedical research have resulted in legal and bureaucratic controls, which has led to certain limits being imposed on researchers (Brodie and Stopani, 1990). Such controls include obtaining informed consent, and submitting projects to institutional review boards for approval. Nevertheless, even after formal recognition of the concept of informed consent in the Nuremberg Code and the Declaration of Helsinki (Kroll, 1993), the need for consent was debated hotly.

The result of this debate is that obtaining informed consent has become an almost universal process in research. The American College of Sports Medicine (1999) stated that

By law, any experimental subject or clinical patient who is exposed to possible physical, psychological, or social injury must give informed consent prior to participating in a proposed project (p. vi).

Given the requirement of informed consent, researchers need to be aware of what the concept involves. Firstly, "informed" implies that potential subjects (or their legal representatives) obtain sufficient information about the project. This information must be presented in such a way that it is matched to the appropriate comprehension level, enabling subjects to evaluate and understand the implications of what they are about to

agree to. Secondly, "consent" implies free, voluntary agreement to participation, without coercion or unfair inducement.

Practically, how do you decide how much information is required to inform someone, and how do you know whether he or she understands the process? These questions point to a difficult, equivocal area, but gathering information on the second question will help to answer the first. Understanding a document is related to its readability, and one way of testing readability is to perform a simple electronic test such as the readability statistics contained in the Microsoft Word spelling and grammar checks. A better method would be to conduct a comprehension check on a representative sample of your subjects (see Cardinal, 2000). The outcome of your checks should then inform your decisions on the level and amount of information you provide to ensure that subjects make a choice that is free, and that the choice is based on sufficient knowledge.

Mahon (1987) stated that consent can be considered to be informed when "...it is given in the full, or clear, realization of what the tests involve, including an awareness... of risk attached to what takes place" (p. 203). According to Zelaznik (1993), "Subjects must be fully informed of the risks, procedures, and potential benefits, and that they are free to end their participation in the study with no penalty whatsoever" (p. 63).

Ethically adequate or acceptable informed consent is obtained if the subject receives full disclosure of relevant information, if this information and its implications are understood, and if the subject voluntarily agrees to the intervention

Elements of an Informed Consent Document

The informed consent form signed by the subject needs to be tailored to the specific project that it relates to. The document should include the following elements:

- an explanation of the purposes of the project;
- a description of the procedures that will involve subjects, including the time commitment;
- identification and description of any risks/discomforts, and potential benefits that can reasonably be foreseen, as well as any arrangements for treatment in the case of injury;
- statements regarding confidentiality, anonymity, and privacy;
- identification of an appropriate individual whom the subject can approach regarding any questions about the research;
- a statement that participation is voluntary, that consent has been freely obtained, and that subjects may withdraw at any time without fear of sanction.

A consent form should not include language that absolves the researcher from blame, or any other waiver of legal rights releasing, or appearing to release anyone from liability (Liehmon, 1979; Veatch, 1989, p. 166). In any event, it is unlikely that such waivers would provide legal protection to researchers or institutions. The consent form should conclude with a statement that the subject has read the document and understands it, and should provide space underneath for his/her signature and the date. Space should also be provided for signatures of the researcher and an independent witness. Informed consent should be given on a written document.

Written consent is now considered to be the norm for all but the most minor of research procedures (South African Medical Research Council, 1993). Written consent can serve to protect subjects as well as investigators. For researchers, a written record serves as proof that some attention has been paid to the interests of the subjects, and may in fact serve as defense in the case of litigation. In addition to providing proof that ethical issues have been considered, written consent is superior to oral in that the form itself can be used as an explanatory tool and as a reference document in the communication process between researchers and subjects. However, when there are doubts about the literacy

level of subjects, verbal information should supplement proxy written consent. Also, presenting information verbally as well as in written form may have the advantage of prompting subjects to ask relevant questions. Witnessed consent may be particularly useful when subjects are elderly or have intellectual or cultural difficulties in speech or comprehension. In these cases, an independent person, such as a nurse or a religious leader, signs a document stating that the witness was present when the investigator explained the project to the potential subject, and that in the opinion of the witness, consent was given freely and with understanding (South African Medical Research Council, 1993).

Special legal or institutional considerations may apply when the research involves pregnant women, fetuses, prisoners, children, wards of the state, or when deception is used. For example, research involving children requires written parental consent as well as the assent of the child. Assent is written or verbal agreement by the child, taking into account the potentially reduced level of comprehension. Research requiring deception or procedures carrying an unusually high risk of harm will typically require that a researcher satisfies additional conditions. For example, justifications for deception would include that the results are unobtainable through other means, that subjects are not harmed, and that thorough debriefing occurs.

There is little unanimity concerning the practice of paying research subjects, particularly when intrusive procedures are involved. Researchers should be satisfied that payment does not constitute coercion. Payment should not adversely affect the judgement of potential subjects in respect of risk assessment. Statements on payment to subjects should not deflect attention away from the other information in the informed consent form.

It is worth noting that obtaining informed consent does not ensure that a research project is ethical. The research itself must be ethical, and researchers should consider the moral issues that apply to their work.

Checklist for Researchers

This checklist should help you meet your obligations to your subjects and your ethical committee. Ensure that you also check the local, regional or national requirements pertaining to informed consent and that you follow them to the letter.

- Make sure that you get voluntary, written, first-person informed consent.
- Check institutional or legal guidelines about parental consent, and about obtaining a child's assent. In the case of using children as research subjects, obtain the necessary parental consent, and the child's assent.
- When using vulnerable populations (e.g., the aged, wards of the state or other agencies), check that you comply with any ethical requirements specific to that group. For example, you may need witnessed consent for cognitively impaired subjects.
- Satisfy yourself that subjects understand the nature of the project, including any risks or potential benefits. Describing the project to them verbally will often assist in this process
- Explain to subjects that they are free to ask questions at any time, and that they can withdraw from the project whenever they want to.
- Make sure that no coercion occurs during the recruitment process. (Here you need to be clear on issues such as the researcher also being a teacher or assessor of subjects' work, for example in the case of students.)
- Allow subjects a "cooling off" period to consider their participation (the time between reading the form and actually agreeing to take part).
- Assess the risk of physical, psychological, or social harm to subjects.

- Provide medical or other appropriate backup in the event of any potential harm in the categories mentioned above.
- Provide medical or other screening, as appropriate.
- Assess the impact of any cultural or gender issues that may pertain to your subjects, and/or the dissemination of your findings.
- Provide adequate assurances regarding privacy, confidentiality, anonymity, and how you will securely store and treat your data.
- Satisfy yourself that any payments or inducements offered to subjects do not adversely influence their ability to make an informed assessment of the risks and benefits of participation.
- If your study involves deception, state the reasons and indicate how you will debrief the subjects about the deception.
- Set measures in place to provide subjects with feedback/information on completion of the project.
- And of course, make sure that you have received approval to proceed from the appropriate institutional ethics committee. If your institution does not have standardized information and consent forms, [download templates](#) (in rich-text format) courtesy of the ethics committee of the University of Otago, and adapt them to your project.

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