Did you know that participation in any research study is voluntary, even if an authority figure asks you to participate?

The Belmont Report states that a subject’s "agreement to participate in research constitutes valid consent only if voluntarily given" and that "the informed consent process requires conditions free of coercion and undue influence."

The regulations at 21 CFR part 50 reiterate the statements in the Belmont Report by stating that subjects are free to participate or decline participation for any reason and that a subject may stop participating at any time (even after signing a consent form). The regulations also stipulate that an investigator must seek consent only under circumstances where the possibility of coercion or undue influence (real or perceived) is minimized.

The U.S. Department of Health and Human Services defines coercion and undue influence as follows:

Coercion: "an overt or implicit threat of harm intentionally presented by one person to another in order to obtain compliance."

Undue influence: "an offer of an excessive or inappropriate reward or other overture in order to obtain compliance."

However, undue influence can be more subtle. An individual may feel pressure to participate when the request to participate comes from someone in an authoritative position, or a student might feel pressure to participate if everyone else in the class is participating.

In addition to the requirements found in the Belmont Report, the regulations (21 CFR part 50) state that declining or stopping participation shall in no way influence any services to which the subject is otherwise entitled. Also prospective subjects or their legally authorized representative should receive sufficient opportunity to consider whether or not to participate in a research study.

The Institutional Review Board is responsible for assuring that the research subject’s rights and welfare are protected. If you have questions or concerns at anytime during participation or after participating in a research study you may contact the Institutional Review Board or the Chief Research Officer.

QUESTIONS?

Send your questions to the PNWU IRB at Research@pnwu.edu
Research Conducted at PNWU by Non-PNWU Investigators:

Universities are often approached by investigators from other universities or health care entities to conduct research at their institution.

When outside researchers request to conduct human subject research at PNWU, a request must be submitted to the Office of Scholarly Activity (OSA) - before any research activities occur (including advertising, recruitment, consent, or data collection). OSA will work with the investigator to obtain the necessary study information. The study documents collected include copies of the study protocol, recruitment plan, consent form, data collection tools, and documentation of IRB review and approval or determination of IRB exemption. Once the necessary documents have been received, the Chief Research Officer (CRO) will determine if PNWU IRB review is necessary and will work with the appropriate individuals to obtain approval.

In addition to the CRO’s approval, the following approvals will be necessary:

- For studies involving our students*—Associate Dean of Student Affairs (ADSA)
- For studies involving our faculty—Human Resources, Dean
- For studies involving our staff—Human Resources

* The Dean must be informed of studies involving students in the COM, although authorization from the Dean is not required if the ADSA has given approval. The CRO will also inform any other parties who should be notified, depending on the nature of any given study.

Once the above approvals have been conveyed to the CRO, a letter of permission, which specifies any conditions placed on the research, will be sent to the investigator. All related study records, materials and correspondence will be maintained by the Office of Scholarly Activity.

Remember, if you are asked to participate in research as a subject, you always have the right to decline without any risk to you for choosing not to participate. — no matter who asks you to participate. And, in most cases, you can withdraw from a study after having agreed to participate. There are exceptions, such as withdrawing after having submitted an anonymous survey. The researchers cannot remove your submission because they cannot identify it as having been from you. Also, if you are receiving a therapy whose withdrawal is risky, the therapy will be appropriately withdrawn or modified to protect your health, but your research data will still be removed from the records even though you’re still receiving the treatment.