Veterans Health Administration
Research & Development
Improving Veterans' Lives — www.research.va.gov

Ethical Considerations:
Informed Consent Process

Informed Consent:

Informed consent reflects the basic principle of respect for persons. This means the person considering participation in a research study should:

- have legal capacity to give consent
- be able to exercise free power of choice without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion
- have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him/her to make an enlightened decision

The person considering participation in research needs to know the nature, duration and purpose of the experiment; the method and means by which it is to be conducted; all risks and discomforts to be reasonably expected; and the effects upon his/her health that may possibly come from participation in the research study.

There is a common misconception that the informed consent document and the informed consent process are one and the same. The informed consent document is one important part of the informed consent process. Informed consent is an ongoing process, not a piece of paper or a discrete moment in time.

Who may obtain informed consent?

VA Policy states that a person knowledgeable about the consenting process and the research to be conducted must obtain the informed consent. If someone other than the Principal Investigator obtains informed consent, the Principal Investigator should formally delegate this responsibility, and the person(s) so delegated should have received appropriate training to perform this activity. This person is also required to complete training on ethical principles of human subject protection and good clinical practice; these two trainings must be completed annually.

Coercion

The person considering participation in research should not feel forced to participate. Investigators are required to make sure study participants understand that taking part is completely voluntary and that they may withdraw at any time. They must also understand that whether or not they participate in the research study, it will not affect their normal standard of care or their benefits.

Commonly Asked Questions and Answers

An essential part of the informed consent process is being able to adequately answer every question presented by the person considering participating in the research study. Informed consent may not be obtained until you have adequately answered all the questions. A list of commonly asked questions and answers could be helpful.

Questions could include:

- Who is doing this study and what questions might it answer?
- What could happen to me, good or bad, if I take part?
- Could my condition get worse during the study? What will happen if it does?
- What other options or choices do I have if I decide not to take part in this study?
- Will I have to make extra trips to the VA?
- Will I be able to continue to see my own doctor?
- Will I be charged anything or paid anything to be in this study?
- What will happen to me at the end of this study?
- Who will find out that I am taking part in this study?

Additional questions can be found in the brochure, "*I'm a veteran. Should I participate in research?*" (available at your local R&D Office).

Contact Information:

Marisue Cody, PhD
Deputy Director
Program for Research Integrity, Development & Education (PRIDE)
VA Office of Research & Development
810 Vermont Ave., NW (12)
Washington, DC 20420
Tel (202) 461-1814
http://www.research.va.gov/programs/pride

VA COACH
Center On Advice & Compliance Help
Helping VA facilities protect veterans in research