

Citizen Scientist Program

Implementation Science Program
University of Florida Clinical and Translational Science Institute
www.ctsi.ufl.edu/about/ctsi-programs/implementation-science
352-294-5992

Informed Consent: Additional Elements Needed, Depending on Research Project

In addition to the required elements of consent covered in the module presentation, there are additional elements that can be added to an informed consent. This depends entirely on the research project in question, as well as the population being examined in the study. (Content courtesy of Dana Leach)

- Number of subjects participating
- Probability of random assignment or placebo placement
- Risks to vulnerable subjects, e.g., embryo, fetus, pregnancy
- Payment for participation (if applicable)
- Additional costs from participation
- Circumstances for investigator “withdrawing” the subject
- Early withdrawal consequences
- Statement regarding how significant new findings will be communicated
- Certificate of Confidentiality (if any)/limitations of certification protection
- HIPAA, also called the Privacy Rule, is a federal law that prohibits health care providers from using or disclosing “Protected Health Information” (PHI) without written consent from the patients.

