Required Elements of Informed Consent
Chaminade University IRB
March 2015
Updated to reflect new Common Rule Guidance January 2018

Effective January 19, 2018, the **requirements for informed consent** will change, with the addition of:

- "Key information" to be presented at the beginning of the consent form
- New consent elements
- Changes to waiver criteria and documentation (plus other process changes)
- A "broad consent" option for unspecified future use of identifiable data/bisopecimens

The intent of these changes is to facilitate the subjects' understanding of the proposed research and also ensure that they understand how their data and biospecimens may be used.

Consent Checklist:
The INFORMED CONSENT MUST:
Include a **Key Information section at the beginning** that addresses the following five factors: (1) the fact that consent is being sought for research and that participation is voluntary; (2) the purposes of the research, the expected duration of the prospective subject's participation, and the procedures to be followed in the research; (3) the reasonably foreseeable risks or discomforts to the prospective subject including physical, psychological, social harm, breach of privacy, discomfort, or inconvenience? (4) the benefits to the prospective subject or to others that may reasonably be expected from the research; and (5) appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject. As a general matter, a brief description of these five factors would encompass the key information most likely to assist a reasonable person (or legally authorized representative) in understanding the reasons why one might or might not want to participate in research
include a statement that the subject may withdraw from the study at any time without penalty?
include who to contact (PI details including email address and telephone) for answers to questions or in the event of a research-related injury or emergency?
If students are participants the Consent must include a clear statement that their participation is voluntary and cannot affect their grade in a class

include a statement that subjects may contact the Chair of the Institutional Review Board for answers to questions regarding their rights as research subjects, and state the contact details for the IRB chair (irb@chaminade.edu)