

## Informed Consent

## Overview, Regulatory Support and References:

Informed consent is the hallmark ethical requirement regarding clinical research with human subjects. Informed consent is not simply a form or a one-time event, but an ongoing process that begins before the subject is enrolled and lasts until after they have completed participation in the research project. Informed consent is the combination of the state of understanding the nature of the research activity and the ability to voluntarily choose whether or not to begin or continue participation. The Informed consent form is an essential part of clinical research and is designed to protect the rights and safety of subjects participating in clinical research. Adherence to ethical principals as well as federal/local laws not only protects both the subject's autonomy but also fosters public trust in the research process to which medical progress is dependent. Strict guidelines are in place for the contents of an ICF that must be adhered to.

All clinical research conducted at NSU, requires an informed consent. Policy and procedures for informed consent are located on the following IRB website: http://www.nova.edu/irb/manual