NOVA SOUTHEASTERN UNIVERSITY
OFFICE OF SPONSORED PROGRAMS
POLICIES AND PROCEDURES

PURPOSE:

To establish a policy and procedure for the protection of human subjects involved in research, to explain the function of the Institutional Review Board (IRB) and its policies and procedures, and to ensure compliance with federal requirements.

DEFINITIONS:

Human Subject: Means a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information.

Interaction: Includes communication or interpersonal contact between investigator and subject.

Intervention: Includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Private Information: Includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Research: Means a systematic investigation, including research and development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

POLICY:

The university is responsible for the protection of the rights and welfare of any human subjects involved in research and will conform to and abide by all scientific and administrative statutes, regulations, guidelines, policies and procedures as required by Department of Health and Human Services (DHHS) regulations at 45 CFR part 46, the Health Insurance Portability and Accountability Act (HIPAA), the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, the Belmont Report, and including all funding agency regulations, *e.g.*, 15 CFR part 27, as applies to National Oceanic and Atmospheric Administration (NOAA) awards).

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REFERENCES:

- Department of Health and Human Services (HHS) regulations at 45 CFR Part 46
- National Institutes of Health regulations and policies, the Health Insurance Portability and Accountability Act (HIPAA), 42 USC 201 note, the National Research Act, 42 USC 201 note, the National Dental Research Act, 42 USC 201 note., The Health Research Extension Act, 42 USC 201 note,, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, and the Belmont Report.
- NIH Grants Policy Statement, http://grants.nih.gov/grants/policy/policy.htm#gps
- NIH Office of Human Subjects Research (OHSR) at http://ohsr.od.nih.gov/
- HHS Office for Human Research Protections (OHRP) at http://www.hhs.gov/ohrp/
- HHS Grants Policy Statement, http://www.hhs.gov/grants/grants/policies-regulations/index.html
- NSF Proposal and Award Policies and Procedures Guide, http://www.nsf.gov/bfa/dias/policy/
- DOC/NOAA regulations, 15 C.F.R. Part 27

PROCEDURES:

The university's IRB policies and procedures are applicable to all sponsored projects as well as all other projects involving human subjects research. The policies and procedures are available at http://nova.edu/irb/manual/policies.html, which includes detailed information regarding:

- History and Purpose of the IRB;
- Policies and Structures;
- Procedures and Processes;
- Training Requirements;
- Research in an Educational Setting;
- Research With Special Populations;
- New/Continuation/Renewal Revision Forms;
- Sample Informed Consent/Assent Forms;
- IRB Waiver of HIPAA Authorization; and
- Adverse Event Report.

Principal Investigators/Project Directors (PIs/PDs) must review all IRB policies and procedures to ensure a thorough understanding of requirements governing research which involves human subjects. All IRB policies, procedures and forms must be followed as directed. If any questions or concerns arise, the PI/PD should contact the IRB Office directly. PI/PD's must obtain IRB approval for projects involving human subjects funded under grants, contracts, cooperative agreements, awards or other agreements before they can initiate any research activity under the award.