NOVA SOUTHEASTERN UNIVERSITY
OFFICE OF SPONSORED PROGRAMS
POLICIES AND PROCEDURES

COMPLIANCE / AWARD ACCEPTANCE
DRUG PURCHASES FOR RESEARCH
EFFECTIVE 12-01-08, REVISED 12-26-2014
POLICY #14

PURPOSE:

To establish the university's guidelines governing the type of drugs purchased for investigational/research purposes, including, but not limited to, research involving human subjects, and to identify and specify the purchasing and handling procedures for such drugs. These drugs may be either prescription or non-prescription drug products. All such prescription drugs are ones that are deemed necessary for medical purposes. Regardless of the above, all drugs purchased will meet legally approved labeling requirements, and acceptable standards of identity, strength, quality, and purity. This policy applies only to drugs purchased for use in research. Drugs purchased for use by or in NSU Clinics, for administration or use in dental, medical, optometry, pharmaceutical, or other health related practice is governed by NSU clinic policies.

DEFINITIONS:

Clinical Trial. A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. There are four phases of clinical trials: Phase 1, in which a small group of individuals are given the investigational drug for the first time to assess safety, and to characterize the drug in terms of pharmacological, pharmacokinetic and toxicological properties; Phase 2, in which a larger group of individuals are given the investigational drug to assess effectiveness, as well as dosage and adverse reactions; and Phase 3, in which large groups of people are administered the investigational drug to confirm its effectiveness, monitor side effects, compare it with standard or equivalent treatments, and collect information that will allow the investigational drug or treatment to be used safely. All three of these phases must be completed prior to marketing approval. Phase 4 studies involve post-marketing surveillance.

Controlled Substance: Means a drug or other substance, or immediate precursor to the drug, included on a Schedule established by the Drug Enforcement Administration in the Department of Justice (DEA). The DEA identifies and designates controlled substances based upon their medical use, potential for abuse, and safety dependence liability.

Drug: A drug as defined by the Federal Food, Drug, and Cosmetic Act (FDCA), and in general, is an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, or an article other than food intended to affect the structure or any function of the body of either man or animals. A drug product, including one that may be dispensed without a prescription, containing one or more active ingredients in a specified dosage form and strength. Each dosage form and strength of a drug is a separate drug.

Drug Classification: The FDCA classified drugs into two categories: Prescription Drugs, ones that are not safe to use except under medical supervision, and Nonprescription [Over-the-Counter (OTC)] Drugs that can be adequately labeled for use by consumers without medical supervision.

Drug Product: A drug product is an article containing one or more drugs (active ingredients) in a specific quantity and manufactured or prepared in a specific dosage form intended for use by humans or other animals, e.g., tablet, capsule, solution, elixir, injectable, aerosol, ointment, cream, etc. Each dosage form and strength (drug quantity) is a separate drug product.

Investigational New Drug (IND): A pharmaceutical manufacturer, researcher, or other sponsor must have an FDA approved IND application prior to administration of any new or off-label drug to humans in clinical trials. An IND is required for each proposed new or off-label drug product and each proposed use of a drug product prior to administration to humans in any clinical trial(s). Drugs approved for a different indication, or investigational combination of drugs requires an IND as well.

New Drug Application (NDA): Prior to marketing of any drug product, a manufacturer must have received an approved NDA from the FDA. NDA's may be approved by the FDA only upon satisfactory evidence that the drug is both safe and effective for the purpose for which it is to be sold. Thus, all drug products legally sold in the United States must have either an NDA, an ANDA (Abbreviated New Drug Application), or SNDA (Supplemental New Drug Application).

POLICY:

Research to be performed at NSU, regardless of source of funding, which involves drugs in any manner, must meet all federal and state laws and regulations concerning licensure, storage, handling, necessary record-keeping, and inspection. See references below.

If controlled substances are proposed to be administered as part of a research protocol or if research is to be conducted on the drugs themselves, researchers/grantees must ensure that the DEA requirements, including licensure, registration, inspection, certification, storage, and record-keeping including purchases, disposition or use, and inventory, as applicable are met. Regional DEA offices can supply forms and information concerning the type of registration required for a particular substance for research use. The main registration office in Washington, DC may be reached at 800-882-9539. Information is also available from the National Institute on Drug Abuse at 301-443-6300.

Clinical research (Phases 1, 2, and 3) involving drugs or devices must meet FDA's IND regulations, FDA's human subject's protection requirements and DHHS's human subject's protection requirements, OSP Policy No. 12 on Human Subjects, and NSU's Standard Operating Procedures for Good Clinical Practice section 17, Accountability of Investigational Product. The official sponsor of the IND, whether NIH or other grantor, or a pharmaceutical manufacturer, or individual researcher or grantee, is legally responsible for meeting the FDA and/or state requirements. If the IND sponsor is a third party, such as a pharmaceutical manufacturer or research organization under contract to a grantee or to a pharmaceutical manufacturer or research organization under contract to a grantor or pharmaceutical firm,, the legal responsibility for monitoring the clinical trial(s) and reporting to FDA rests with the sponsor rather than the grantee. This is generally true for larger, multi-site clinical trials. In "investigator-initiated clinical research," the grantee or the Principal Investigator (PI) is the responsible holder of the IND, and serves as

the sponsor and assumes legal responsibility. In any case, the grantee or PI is ultimately responsible to NIH or other grantor for ensuring compliance with the requirements for protection of human subjects, including compliance with FDA requirements.

Since Phase 4 clinical trials involve marketed drugs rather than investigational drugs, INDs are not required, although human subject requirements, including HIPAA regulations and appropriate record-keeping requirements must still be met by the grantee or investigator. Note that Phase 4 studies are limited to drug uses, dosages, and dosage forms, including route of administration, for which an NDA has been approved by FDA. Any research on drugs which investigate changes in potential use, dosage, or dosage form require an IND even if the drug is legally marketed.

The university will not purchase drugs classified by the FDA as "ineffective" or "possibly effective." (Drugs purchased or prescribed and dispensed by the university will be approved by the appropriate Pharmacy Committee for inclusion in its formulary). These drugs will include those items that have been properly requested and researched, and which are deemed necessary for the proper practice of medicine. All drugs will meet acceptable standards of identity, strength, quality, purity, and effectiveness, and will be purchased at the lowest cost available, when possible, through one of the university's pharmacies.

Please review the references, below, for additional guidance.

REFERENCES:

- NIH Grants Policy Statement, http://grants.nih.gov/grants/policy/policy.htm#gps
- HHS Grants Policy Statement, http://www.hhs.gov/grants/grants/policies-regulations/index.html
- HHS Protection of Human Subjects, 45 CFR part 46
- PHS Policies on Research Misconduct, 42 CFR part 93
- FDA Protection of Human Subjects, 21 CFR part 50
- FDA Financial Disclosure by Clinical Investigators, 21 CFR part 54
- FDA Institutional Review Boards, 21 CFR part 56
- FDA Investigational New Drugs, 21 CFR part 312
- DEA Controlled Substances, 21 CFR parts 1300-1316
- NSU Office of Clinical Research Policies for Good Clinical Practice (http://www.nova.edu/ocr/policies-for-gcp/policies-for-good-clinical-practice.html)

PROCEDURES:

1. The Institutional Review Board (IRB) is responsible for reviewing all research protocols and investigator qualifications to ensure compliance with requirements for protection of human subjects, including compliance with FDA and DEA requirements, HIPAA regulations, and informed consent forms and with state requirements for drug administration and use, including

licensure limitations, as applicable. See OSP Policy No. 12 – *Protection of Human Subjects in Research*.

2. The PI and/or co-Investigator physician is responsible for approving all drug purchases on sponsored projects.