Nova Southeastern University
Standard Operating Procedure for GCP

Title: Institutional Review Board		Version # 1
SOP Number: OCR-IRB-001	**Effective Date: August 2013**	**Page 1 of 1**

PURPOSE: Prior to their undertaking, all clinical research activity (protocol, advertisements etc.) must receive a favorable opinion from the NSU IRB, whose sole interest is the protection of human subjects.

POLICIES:

1. Center/College may not under any circumstance engage in clinical research activity until it has been approved or waived by the IRB. This is not limited to drugs and devices, but also includes studies of data, registry studies, genetic banking, psychology studies etc.
2. The NSU IRB shall review the following:
   - 2.1. Any research activity NSU is engaged in. NSU becomes "engaged" in human subjects research as evidenced by either:
     - 2.1.1. Its employees, agents (including all individuals performing institutionally designated activities or exercising institutionally delegated authority or responsibility) space, systems, technology or equipment does either of the following:
       - 2.1.1.1. Intervenes or interacts with living individuals for research purposes; or
       - 2.1.1.2. Obtains individually identifiable private information for research purposes
     - 2.1.2. Funds are paid by or to the institution for research purposes; OR
   - 2.2. Requests for a waiver of the written authorization requirement imposed by the federal Health Insurance Portability and Accountability Act ("HIPAA") for a specific study, if the study is eligible for review by the IRB under any one of the Center/College-related circumstances listed directly above.
   - 2.3. If there is any doubt as to if an activity is required to be reviewed by an IRB, the IRB Administrator shall be consulted.