NOVA SOUTHEASTERN UNIVERSITY

Nova Southeastern University
Standard Operating Procedure for GCP

Title: ICH Guidelines for Study Personal		Version # 1
SOP Number: OCR-GEN-05	Effective Date: August 2013	Page 1 of 1

PURPOSE: All study personnel- Sub-Investigators, study nurses, administrators and members of supporting departments (eg. The pharmacy) –need to be fully informed about the study. Regular team meetings should be held to review activities and progress.

PROCUDURE:

1. Investigator – A person responsible for the conduct of the trial site. If a trial is conducted by a team of individuals at a site, the investigator is the responsible leader of the team and may be called the Principal investigator.

2. Sub investigators – Any individual member of the clinical trial team designated and supervised by the investigator at the trial site to perform critical trial related procedure and/or to make important trial-related decisions (eg., associates, residents, research fellows).

3. The investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties.

4. The investigator should have available an adequate number of qualified staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely.

5. The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product, and their trial-related duties and functions.

6. A qualified physician (or dentist, when appropriate), who is an investigator or a sub-investigator for the trial, should be responsible for all trial-related medical (or dental) decisions.