Nova Southeastern University
Standard Operating Procedure for GCP

Title: Planning Meetings		**Version # 1**
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PURPOSE: The purpose of this Standard Operating Procedure (SOP)for GCP is to develop and document the operating partitions of the research site and the potential interactions that will occur between these departments and the Sponsor for a selected clinical trial.

POLICIES: A meeting will be held at the start of any clinical trial to discuss and determine the responsibilities and duties of all research site staff that will be involved in the up-coming clinical trial. By documenting the different staff responsibilities in any given clinical trial it will increase the efficiency of the conduct of the trial.

PROCEDURES FOR PLANNING MEETINGS:

1. DETERMINE WHICH STAFF WILL BE DIRECTLY INVOLVED IN THE UP-COMING CLINICAL TRIAL AND THOSE OTHER PERSONS THAT MAY HAVE A VESTED INTEREST IN THE STUDY. THESE WILL INCLUDE BUT ARE NOT NECESSARILY LIMITED TO:

    1.1 Principal Investigator

    1.1.1. Study Coordinator

    1.1.2. Sub-Investigator

    1.1.3. Alternate Study Coordinator

    1.1.4. Recruitment Officer

    1.1.5. Regulatory Agent

    1.1.6. Secretary or Patient Scheduler

    1.1.7. Representatives from out-side agencies that may need to be directly involved.

2. Determine the best time for a meeting as determined by the work schedules of the staff involved.
3. The following items should be discussed with action items defined for each required activity:
   3.1. Protocol review
      3.1.1. Identify required procedures.
   3.2. Staffing requirements
      3.2.1. Assign specific duties to appropriate staff.
      3.2.2. Assure that the education and qualification of the assigned staff meet the needs of the protocol.
   3.3. Timelines
      3.3.1 Date for Investigators Meeting.
         3.3.1.1. Define who will attend the meeting.
      3.3.2. Date to be prepared for IRB submission.
         3.3.2.1. Define who is responsible for the submission and IRB continued follow-up.
   3.3.3 Estimate the date of Sponsor's Study Initiation Meeting.
   3.3.4. Date to start recruitment activities.
      3.3.4.1 Estimate date of IRB approval to start recruitment activities.
   3.3.5. Date for first subject first visit.
   3.3.6. Length of time for subject recruitment.
   3.3.7. Length of time for maintenance phase of trial.
   3.3.8. Estimated date of study completion.
   3.4. Supplies
      3.4.1. Determine what specific supplies will be required for this clinical trial and if any purchases are necessary.
      3.4.2. Determine storage needs for supplies.
         3.4.2.1. E.g. CRFs, lab kits equipment, etc.
   3.5. Clinic space and scheduling
      3.5.1. Discuss the frequency and length of subject visits to determine scheduling requirements.
         3.5.1.1. Scheduling may include time in the lab.
4. Follow-up

4.1 It will be important to determine that the assigned tasks are being completed on schedule.

   4.1.1 Evaluate if additional staff is required to complete critical tasks

on schedule.

4.2 b. Evaluate if the Sponsor's timelines have changed for the project.

4.2.1. Potential Sponsor delay's can have a financial impact on the clinic resources.