Nova Southeastern University
Standard Operating Procedure for GCP

Title: Review of Protocol (Industry) for Suitability for the Center/College		Version # 1
SOP Number: OCR-PRO-002	**Effective Date: August 2013**	**Page 1 of 2**

PURPOSE: The purpose of this SOP is to describe the process of reviewing the protocol of a potential clinical trial and assess if the Center/College has the available resources to conduct the trial for the Sponsor. This SOP requires a great deal of evaluative assessment. The initial step requires the Center/College to fully understand the Center/College requirements of any given protocol and translate these requirements into the Center/College ability to do the trial. It will also be essential to determine if the clinical trial meets the scientific, ethical and financial merits of the Center/College.

POLICIES:

1. Key Research Interests:
    - 1.1 Determine if this protocol is compatible with the Center/ College expertise in the therapeutic areas specialised by the research clinic.
        - 1.1.1 This can usually be determined by reviewing the title of the protocol, protocol summary and introduction.

2. Access to target patient population:
    - 2.1 Estimate the number of patients in the current Center/College database that could potentially qualify for this clinical trial. This can be achieved by running the diagnosis code (ICD-9)
    - 2.2 Evaluate the potential to recruit additional subjects from outside sources
        - 2.2.1 Determine the target patient population by reviewing the subject selection and inclusion/exclusion criteria in the protocol.
3. Staffing Needs:
    - 3.1 Evaluate the availability, ability, experience and current work load of in-house staff to perform the required procedures

dictated by the protocol.

3.1.1 Review the time and events schedule and procedures in the protocol to determine work load and time commitment estimated for this protocol.

3.1 Determine the time commitment that will be required for related activities such as IRB submissions, document and records handling and processing, monitoring visits, and potential audits.

3.2.1 Review the monitoring schedule outlined in the protocol.

3.2 If there are insufficient in-house human resources, are there available consultants to out source certain parts of the protocol.

4 Internal Facility Requirements:

4.1 Compare the requirements of the potential protocol with the physical capabilities of the Center/College.

4.1.1 E.g. how many subjects will need to be seen on any given day, how many visits will be required, etc?

4.1.2 Review the time and events schedule and procedures sections of the protocol to determine requirements.

4.2 Perform feasibility to estimate capacity of the Center/College To manage patient throughput in accordance with the potential clinical trial.

4.3 Analyze any special needs of potential patients.

5. Ancillary Agencies:

5.1 Determine the requirements for other agencies that would be a requirement of the procedures outlined in the protocol.

5.1.1 E.g. laboratory, X-Ray, ECG, Hospitals or other clinics.

6. **SEE ATTACHED FORM – Protocol Feasability Assessment Checklist**

PROTOCOL FEASABLITY ASSESSMENT CHECKLIST

Protocol Title: _____

Study Article(s): _____ **Phase:** _____

Therapeutic Area (Disease): _____

1. General

Does the protocol meet the research site's area of expertise? ❑ Yes ❑ No
Is the number of patients to be enrolled realistic for this site? ❑ Yes ❑ No
Number of subjects to be recruited by research site _____
Are the preparation time lines for this protocol realistic? ❑ Yes ❑ No
Is the enrolment period realistic for this site? ❑ Yes ❑ No
Do the inclusion/exclusion criteria fit with research site patient population? ❑ Yes ❑ No
Will we have to recruit subjects from outside? ❑ Yes ❑ No
Comments: _____

_____

_____

Will our IRB have problems with any aspects of this protocol? ❑ Yes ❑ No
Comments: _____

_____

_____

_____

2. Procedures/clinical assessments

Are frequent observations/procedures required? ❑ Yes ❑ No
Comments: _____

_____

Is the visit schedule flexible? ☐Yes ❑ No
Comments: _____

_____

_____

Are there multiple follow-up visits required? ❑ Yes ❑ No
Are procedures/clinical assessments difficult? ❑ Yes ❑ No
If yes, describe: _____

_____

_____

Estimated monitoring visit schedule time requirements: _____
Frequency of visits: _____
Estimated total number of visits: _____
Can we hand the volume of visits in the current research site schedule? ❑ Yes ❑ No
Other considerations of this protocol that might be a time/staffing factor: _____

_____

_____

Current staff available for this protocol:
Principal Investigator: _____

Study Coordinator: _____

Lab technician: _____

Other Staff required: _____

Is additional staffing/specialist involvement needed? ❑ Yes ❑ No

Comments: _____

_____

_____

1. **Study population**
   - Adults capable of giving consent ❑ Yes ❑ No
   - Adults but consent process compromised ❑ Yes ❑ No
   - Geriatric adults ❑ Yes ❑ No
   - Minors ❑ Yes ❑ No

Comments: _____

_____

_____

4. Case report forms (if CRF available)

How many pages is the CRF?	_____	
Is con medication documentation detailed and or repetitive?	❑ Yes	❑ No
Is adverse event documentation complex?	❑ Yes	❑ No
Are diaries detailed?	❑ Yes	❑ No
Do the diaries need to be transcribed?	❑ Yes	❑ No
Is the study article dispensing/accountability complicated?	❑ Yes	❑ No

Comments: _____

_____

_____

_____

5. Other considerations

Will our patient population benefit from the study?	❑ Yes	❑ No
Is this study desirable to do from a scientific standpoint?	❑ Yes	❑ No

Comments: _____

_____

_____

_____

_____

Do you recommend that the study be conducted at the research site? ❑ Yes ❑ No

Comments: _____

_____

_____

_____

_____ _____/_____/_____

Signature Date