Standard Operating Procedures
*C*linical and *T*ranslational *R*esearch *C*enter

Title:	**Initiation and Management of Protocols**		
Approved By:	Christina Wang MD	**Effective Date:**	March 19, 2012
Number of Pages:	Page 1 of 4	**Revised Date:**	

Purpose: CTRC will provide services in a manner which insures the delivery of safe, competent, effective and efficient care consistent with the Clinical and Translational Science Institute philosophy and good clinical practices.

The professional clinical research nurse will assume responsibility and accountability for promoting interdisciplinary collaboration with the research team.

Policy:

A. Investigators utilizing the Clinical and Translational Research Center (CTRC) are required to demonstrate the following:

1. Current Institutional Review Board (IRB) approval, which includes the most current version of the approved consent.
2. Completed CTRC application on Webridge/Imedris with services requested.
3. Current approval by the CTRC scientific advisory committee (SAC).
4. Copy of approved protocol, CTRC application, Data and Safety Monitoring Plan and consent on file.

5. Completed and signed Physician orders for each subject.

6. Copy of consent signed by subject and investigator before any services are initiated.

7. Completed and signed Inclusion/Exclusion form for each subject.

8. A medical history and physical obtained on CTRC subjects as required per protocol and/or per institution .

B. The Clinical and Translational Research Center (CTRC) requires all Investigators utilizing the CTRC to complete the following prior to scheduling any subjects:

1. Have a scheduled "start-up" meeting with Principal Investigator, study team and designated CTRC staff to develop a study plan specific to the protocol.

2. The plan will include physician orders, protocol visit instructions (forms/flow sheets), laboratory processing instructions and all other pertinent study forms.

3. The principal investigator will review and sign off on all forms used for the study to include: orders, visit records, flow sheets, procedures, lab processing instructions and any other forms used for the study per institution.

4. Staff educational needs will be determined relevant to the study objectives and plan. The principal investigator will meet with the CTRC staff prior to scheduling subjects to complete in-service on any new protocol procedures.

C. For all Subjects seen in the CTRC:

1. Copy of consent signed by subject, and investigator on file.

2. Signed physician orders for subject. For physician orders that are longer than one page, the physician is expected to initial the bottom of each page and sign/date at the end.

3. History and Physical when necessary.

4. Concomitant medications list, when necessary.

5. Name and contact numbers for Principal Investigator or his designated physician in charge for the day.

6. For studies determined by SAC that MD does not need to be present on the unit during study visit - Must have name and contact number of the physician responsible for protocol if different from the Principal Investigator.

7. For studies determined by SAC that MD must be present – Medically responsible physician for the study must be in the CTRC during conduct of the study.

D. Contents of CTRC Subject Charts/Files (Per Institution)

1. Copy of signed consent, including documentation of consenting if subject was consented in the CTRC.

2. Signed physician orders for subject. For physician orders that are longer than one page, the physician is expected to initial the bottom of each page and sign/date at the end.

3. Inclusion Exclusion form, completed and signed by physician investigator. (Cedars Sinai CTRC)

4. Data collection forms and protocol visit flow sheets developed to facilitate data collection.

5. History and Physical if subjects expected to be seen more than once for visits other than blood draw visits, or for subjects receiving medication infusions or moderate risk procedures.

6. Single blood draws require only copy of the signed consent and signed physician orders.

III. IMPLEMENTING THE INTERVENTIONS PRESCRIBED IN THE PROTOCOL STUDY PLAN

A. Interventions are consistent with the approved study protocol.

B. Interventions are implemented in a safe and appropriate manner.

C. Interventions are documented.

D. The participant's immediate condition or needs and the measurements stipulated in the research plan determine the priority of data collection.

E. Data are collected using appropriate tools and techniques and are according to study timelines.

F. The data collection is systematic.

G. Data are documented in a retrievable and verifiable form.

IV. EVALUATES THE PARTICIPANT'S RESPONSES

A. The participant's responses, including adverse events, to research interventions is systematic and ongoing.

B. Evaluation of the participant's continuing eligibility to participate in the research is systematic and ongoing.

C. The participant, investigator and other research team members are involved in the evaluation process.

D. Revisions in the method of study plan implementation and data collection are completed and evaluated in a timely manner.

E. Evaluation of the participant's knowledge about the research plan is systematic and ongoing.

References:

Appendices: