IRB Date: Agenda Item#: IRB #

PI:

IRB Continuing Review Checklist

***Instructions to Reviewers**: In your evaluation, check each item listed whether A* (acceptable) N*(non-substantive correction) or S*(substantive correction). This checklist will be forwarded to the principal investigator for completion of the checked items prior to receiving continued approval.*

I. ☐ This renewal request does not involve continued recruitment of subjects. [Remainder of checklist does not apply. Consent form will not be updated.]

II. The following questions refer to the "Outline of Research Reports" and the most recently approved version of the informed consent document for study cited above:

A*N*S*

☐ ☐ ☐ (A) Adverse Effects reported are not sufficiently described in the consent document. The consent document needs to be revised to include those circled on the PI's Report Form.

☐ ☐ ☐ (B) The consent document does not reflect all Modifications (amendments) that pertain to subject participation and safety. See those circled on the PI's Report Form.

III. The consent document should reflect current IRB standards with regard to basic IRB standards and current regulations, as described in the following list:

A. The 8 basic elements of informed consent: Any item checked below needs to be added or corrected:

☐ ☐ ☐ 1. A statement that the study involves research, with an explanation of the purpose and procedures.
☐ ☐ ☐ 2. A description of reasonably foreseeable risks or discomforts.
☐ ☐ ☐ 3. A description of any benefits to the subject or to other which may reasonably be expected.
☐ ☐ ☐ 4. Disclosure of appropriate alternative procedures, if any.
☐ ☐ ☐ 5. Description of extent to which confidentiality will be maintained.
☐ ☐ ☐ 6. If greater than minimal risk, an explanation of compensation or medical treatment available if injury occurs.
☐ ☐ ☐ 7. Identification of three contacts (position or name, phone numbers): (1) contact for answers to pertinent questions, (2) 3rd party impartial contact regarding rights and complaints, (3) research related injury.
☐ ☐ ☐ 8. Assurance that participation is voluntary, refusal or discontinued participation at any time will involve no penalty of loss of benefits.

B. Minimal current information is required (*Note to IRB Reviewer – these are all NON-SUBSTANTIVE ITEMS):*

☐ ☐ 1. Local telephone numbers must be updated, including use of '558' numbers. Frequently needed numbers: LLUMC central switchboard is 558-4000, paging is 558-1717.
☐ ☐ 2. Change language that confuses care-giving activities with research activties:
☐ ☐ Change "medicines" or "drugs" to "study drugs".
☐ ☐ Change "doctor" or "physician" to "study doctor".
☐ ☐ Change "patient" to "subject" or "participant".
☐ ☐ 3. Update 3rd party contact as follows:
Office of Patient Relations, Loma Linda University Medical Center, Loma Linda, CA 92354, phone (909) 558-4647.

Select Reviewer

Other Comments: