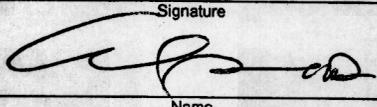
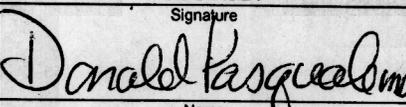
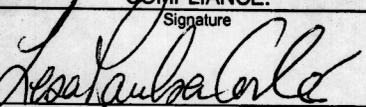


Stratton VA Medical Center IRB Standard Operating Procedure

TITLE: <b>Processing of Deviations</b>		DOCUMENT NUMBER: <b>IRB-015</b>	
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IRB CHAIR OR DESIGNEE:	ACOS R&D:	COMPLIANCE:
<small>Signature</small> 	<small>Signature</small> 	<small>Signature</small> 
<small>Name</small> Gina Feltman	<small>Name</small> Donald Pasquale	<small>Name</small> LES PAULSEN
<small>Date</small> 5/17/04	<small>Date</small> 5-17-04	<small>Date</small> 5-17-04

**1 POLICY**

It is Stratton VA Medical Center's policy to comply with all applicable local, state and federal regulations, and ICH guidelines in the conduct of clinical research studies. Written procedures are required for processing reports of deviations.

The IRB's policy requires the Principal Investigator to report to the IRB any "Significant Deviation" to the IRB-approved protocol that may potentially affect the rights, safety, and welfare of the subjects, such as:

- Administrative or procedural infractions in the implementation of the protocol or informed consent.
- Significant changes to the IRB-approved protocol that may potentially affect the rights, safety, and welfare of the subjects.

All changes in previously approved protocols must be promptly reported to the IRB. The proposed changes must not be initiated without review and approval except where necessary to eliminate apparent immediate hazards to subjects.

The Principal Investigator(s) may contact the IRB Chair or designee with questions regarding whether or not a potential deviation poses a risk to subjects. The IRB will make the final determination as to the level of risk.

**2 DEFINITIONS**

**Deviation:** Any departure from the procedures stated in the approved research protocol or informed consent without prior review and approval of the modification.

**"Significant Deviations":** Any departure from the procedures stated in the approved research protocol or informed consent that increases the risk to subjects. The deviation is required to be reported to the IRB within 5 days of the incident. Examples include but are not limited to the following:

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- a. Infractions involving dosing/distribution of study medications causing risk to the subject
- b. Infractions in following the guidelines for proper informed consent execution (i.e. using an expired informed consent)
- c. Infractions in which the sponsor (if applicable) requests notification to the IRB
- d. Infractions in which research procedures performed outside the approved research protocol increased risk to subjects

"Non-Significant Deviations": Any departure from the procedures stated in the approved research protocol or informed consent that pose no increased risk to the subjects and do not require reporting to the IRB. Examples include but are not limited to the following:

- a. Infractions involving expected concomitant medication deviations
- b. Infractions involving missed/late visits or study procedures that pose no increased risk to the subject (i.e. a missed 3<sup>rd</sup> blood draw – exception: if the PI should determine a 3<sup>rd</sup> blood draw is not needed for all participants, a revision/amendment to the protocol would be required)
- c. Infractions involving unintentional clerical errors on the informed consent (i.e. subject identifiers are not on all pages)

### 3 MATERIAL

IRB-003 "Suspension and Termination of Approved Research by the IRB"

### 4 PROCEDURE

- 4.1 Principal Investigators may report "Significant Deviations" to the IRB by submitting a letter that will include, but is not limited to, the following: a description of the deviation, an explanation of why the deviation occurred, a corrective action plan, and an explanation of what is being done to prevent a future occurrence. If the study is a sponsored study, the letter should indicate if the sponsor was notified of the deviation.
- 4.2 Upon receipt of the deviation letter, the IRB staff stamps it with a date of receipt. The information is reviewed for completeness and accuracy by the IRB staff and is entered into the database.
  - 4.2.1 If any items are missing or there are questions about the deviation, the Principal Investigator or the designated contact person may be contacted by the IRB staff and requested to provide additional information or documents.
- 4.3 The IRB Chair or designee will review the deviation letter to determine whether any revisions or actions are required and if so, will refer the deviation to the full

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IRB to review and determine the actions required. The IRB is notified of all "significant deviations" in the agenda of the next scheduled IRB meeting.

- 4.4 If the IRB Chair or designee or the full IRB request any modification to the consent document or research protocol, or addendum consent, the IRB Chair or designee will send a notification to the Principal Investigator to submit the modifications to the IRB for review. If the IRB does not receive the complete modification or a satisfactory explanation as to why the modification could not be completed within four weeks,
- 4.4.1 The Principal Investigator is sent a Notification indicating failure to comply with a request for modification. A copy will be sent to the Care Line Leader and the institutional official.
- 4.4.2 The research is suspended following IRB-AD-003 "Suspension and Termination of Approved Research by the IRB."
- 4.4.3 The Principal Investigator becomes ineligible to submit new protocols.
- 4.4.4 The Principal Investigator remains ineligible until a complete modification is received by the IRB and all other deficiencies are resolved.
- 4.4.5 The list of ineligible Principal Investigators will be distributed to IRB members with the agenda and included with the meeting minutes.
- 4.5 If the IRB Chair or designee or the full IRB determines that a significant deviation requires reporting, then
- 4.5.1 The IRB staff prepares a report of the event and corrective actions to be taken.
- 4.5.2 The IRB staff sends a copy of the report signed by the IRB Chair or designee to the Care Line Leader and the institutional official.
- 4.5.3 A copy of the report is included with the agenda for the next scheduled IRB meeting.
- 4.5.4 The IRB staff forwards a copy of the notification to Office for Human Research Protections (OHRP), Food and Drug Administration (FDA), Office for Research Oversight (ORO), and the sponsor, as applicable, within 10 working days of the IRB's determination.