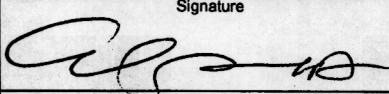
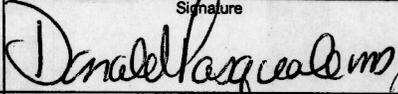


Stratton VA Medical Center IRB Standard Operating Procedure

TITLE: <b>Suspension and Termination of Approved Research By the IRB</b>		DOCUMENT NUMBER: <b>IRB-003</b>	
REVISION NO.: 01	SUPERSEDES/DATE: 00/10-30-03	EFFECTIVE DATE: May 14, 2004	PAGE 1 OF 4

IRB CHAIR OR DESIGNEE:	ACOS R&D:	COMPLIANCE:
Signature 	Signature 	Signature 
Name Fishman	Name Donald Pasquale	Name LESA PAULSEN-CORTES
Date 5/11/04	Date May-13-04	Date 5-14-04

**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 to suspend or terminate approved research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious risk or harm to subjects. Written procedures are required for reporting the suspension or termination to the investigator, appropriate institutional officials, and applicable federal agencies and sponsors.

**2. DEFINITIONS**

**Institutional Review Board (IRB):** The Stratton VA Medical Center Institutional Review Board, formally designated by Stratton VA Medical Center to review, to approve the initiation of, and to conduct periodic review of biomedical research involving human subjects.

**IRB Staff:** Members of the Research Office who support the functions of the IRB.

**Principal Investigator(s):** Individual(s) who actually conducts a research investigation under whose immediate direction research is conducted, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of the team.

**Suspension of research:** A directive of the IRB or the IRB Chair or designee to temporarily or permanently stop some or all recruitment, or some or all of the research activities.

**Termination of research:** A directive of the IRB to withdraw approval for research.

**3. FORMS**

None

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#### **4 REFERENCES**

- 45 CFR 46
- 21 CFR 50, 56
- 38 CFR 16
- VHA Handbook 1200.5 Requirements for the Protection of Human Subjects in Research
- ICH Harmonised Tripartite Guideline For Good Clinical Practice (1 May 1996)

#### **5 PROCEDURE**

##### **5.1 Authority to suspend or terminate research**

5.1.1 The IRB may suspend or terminate some or all approved research conducted by a Principal Investigator when:

5.1.1.1 The research is not being conducted in accordance with IRB requirements; or

5.1.1.2 The research is associated with unexpected serious risk or harm to subjects; or

5.1.1.3 There is an investigation as to whether research should be terminated or suspended, and there is reasonable concern that subjects are at increased risk pending the outcome of the investigation.

5.1.2 The IRB Chair or designee may temporarily suspend some or all approved research conducted by a Principal Investigator when:

5.1.2.1 There is reasonable concern that subjects are at increased risk and there is inadequate time for convening an IRB meeting to determine if a suspension should take place.

5.1.3 If the IRB Chair or designee suspends or terminates any approved research:

5.1.3.1 The research will be placed on the agenda of the next scheduled IRB meeting.

5.1.3.2 The IRB will approve, modify or reverse the suspension or termination.

##### **5.2 Subject protection after suspension or termination**

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5.2.1 If approved research is suspended or terminated, the IRB will consider alternatives that protect subjects currently enrolled in the research.

5.2.2 When required for subject safety, the IRB Chair or designee will directly notify Principal Investigators of suspension or termination of approved research. If the Principal Investigator is unavailable, the IRB Chair or designee will directly notify the Care Line Leader and institutional officials about the suspension or termination of approved research.

5.2.3 Once notified of the suspension, the investigator must immediately submit to the IRB Chair or designee a list of research subjects for whom suspension of the research would potentially cause harm. The IRB Chair or designee, in consultation with the Chief of Staff (COS), will determine if the subjects may continue in the research.

5.3 Reporting of suspension or termination

5.3.1 The IRB staff will send to Principal Investigators a written notification of suspended or terminated research within 5 business days of the decision.

5.3.1.1 The reasons for the suspension or termination will be included in the notification.

5.3.1.2 For suspended research, enrollment of new subjects cannot occur. The IRB, or IRB Chair or designee, in consultation with the COS, will determine if continuation of research interventions for enrolled subjects should continue.

5.3.1.3 A copy of the notification will be sent to the Care Line Leader and appropriate institutional officials, such as the Medical Center Director, the Chief of Staff, and Research Compliance Officer.

5.3.2 If the DHHS regulates the research, the IRB Chair or designee will forward a copy of the notification to OHRP within 10 business days of the decision.

5.3.3 If the FDA regulates the research, the IRB Chair or designee will forward a copy of the notification to the FDA within 10 business days of the decision.

5.3.4 The IRB Chair or designee will forward a copy of the notification to Office of Research Oversight (ORO) within 10 business days of the decision.

5.3.5 If a federal agency other than FDA or OHRP funded the research, the IRB Chair or designee will forward a copy of the notification to the applicable federal agency within 10 business days of the decision.

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5.3.6 If a sponsor other than a federal agency funded the research, the IRB Chair or designee will forward a copy of the notification to the sponsor within 10 business days of the decision.

5.4 Removal of suspension

5.4.1 The investigator will submit a written response to the IRB within 30 days of the date of the suspension letter. In the response, the investigator must provide justification for the removal of the suspension.

5.4.2 The letter of justification will be reviewed at the next scheduled IRB meeting. The IRB will make a determination to lift the suspension, maintain the suspension with conditions, or terminate the study.

5.4.3 IRB review and re-approval must occur prior to re-initiation of the research.

5.5 Records

5.5.1 The date the approved research is suspended or terminated by the IRB is recorded in the database.

5.5.2 The file is removed from the active files to be processed for termination by R&D. The file is then labeled as terminated and stored for at least three years after termination.