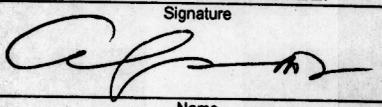
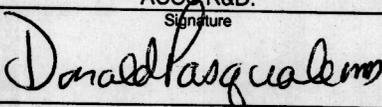


Stratton VA Medical Center IRB Standard Operating Procedure

TITLE: <b>Termination of Research by an Investigator</b>		DOCUMENT NUMBER: <b>IRB-004</b>	
REVISION NO.: 01	SUPERSEDES/DATE: 00/10-8-03	EFFECTIVE DATE: May 14, 2004	PAGE 1 OF 3

IRB CHAIR OR DESIGNEE:	ACOS R&D:	COMPLIANCE:
<small>Signature</small> 	<small>Signature</small> 	<small>Signature</small> 
<small>Name</small> Z. Fishman	<small>Name</small> Donald Pasquale	<small>Name</small> LESA PAULSEN CORDES
<small>Date</small> 5/11/04	<small>Date</small> May-13-04	<small>Date</small> 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 for investigator - initiated termination of research.

**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 Chair designee:** An IRB member with one or more years of experience on the IRB.

**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.

**3 FORMS**

Protocol Progress Report Form  
Notification of Termination

**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)

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## 5 PROCEDURE

- 5.1 Termination of a research protocol requires a completed Protocol Progress Report Form with a request for termination by the Principal Investigator(s).
- 5.2 If a Principal Investigator(s) requests termination of a protocol and has not submitted a completed Protocol Progress Report Form with a request for termination, the IRB staff provides a Protocol Progress Report Form to the Principal Investigator(s).
- 5.3 The Principal Investigator(s) is expected to complete the progress report form and provide all applicable attachments requested on the form.
- 5.4 Upon receipt of a progress report from a Principal Investigator(s) requesting termination, the IRB staff stamps it with the date of receipt and enters the request into the database.
- 5.5 The IRB staff checks the progress report for completeness and accuracy.
- 5.6 The IRB staff compares the progress report with previous progress reports.
  - 5.6.1 Verify that the subject lists for current and previous progress reports are consistent with the approved number for total enrollment.
  - 5.6.2 Verify that the progress report accounts for any serious adverse events of subjects at Stratton VA Medical Center and its affiliates for which the Research Office received written summaries.
  - 5.6.3 Verify that the Research Office received written summaries for any serious adverse events mentioned in the progress report.
- 5.7 If any items are missing or questions have been answered unsatisfactorily, a member of the IRB staff will notify the Principal Investigator(s). The IRB staff will not process the paperwork until corrections have been made.
  - 5.7.1 The IRB and/or IRB staff can use sources other than the Principal Investigator(s) for verification of information in the progress report, such as Data Safety Monitoring Board reports, independent audits, or investigative subcommittees to determine that no material changes have occurred since the previous IRB review.
- 5.8 If requests for additional information are inadequate or additional requested items are still missing, then the protocol is sent to the full committee for review of the termination and recommended action on the inadequate information or missing items.

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- 5.9 Once the progress report is complete, the IRB Chair or designee reviews the request for termination, and signs the Notification of Termination letter. The date that the Notification of Termination letter is signed is the date of termination.
- 5.10 The Notification of Termination letter is sent to the Principal Investigator(s) and a copy is put in the file.
- 5.11 The termination of the protocol is listed in the agenda of the next scheduled IRB meeting.
- 5.12 The date the research is terminated by the IRB is recorded in the database. 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.
- 5.13 Principal Investigator(s) may reopen research they have terminated by following the procedures for initial review of research.