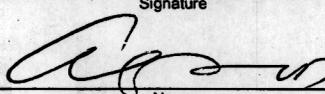
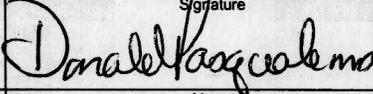
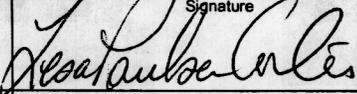


Stratton VA Medical Center IRB Standard Operating Procedure

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IRB CHAIR OR DESIGNEE:	ACOS R&D:	COMPLIANCE:
Signature 	Signature 	Signature 
Name 788urner	Name Donaco Passuale	Name LESA PAULSSA-CORTES
Date 5/5/04	Date 5-11-04	Date 5/12/04

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 used to guide personnel through various procedural steps and standardize practices to ensure subject protection and promote responsible 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 or designee: The person responsible for the oversight of the review functions of the IRB.

Good Clinical Practice (GCP): A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

Research Compliance: The person or organizational element, except the Principal Investigator, designated by management to perform the duties relating to quality assurance and compliance of clinical research studies.

Standard Operating Procedure (SOP): A procedure written in standardized format, giving detailed instructions, which describe a routine activity so that each person following the SOP will perform the activity in a consistent and repeatable manner. The SOP author is responsible for technical content of the SOP.

3 FORMS

IRB Standard Operating Procedure Master Log

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SOP Scheduled Review Notice form

4 REFERENCE DOCUMENTS

N/A

5 PROCEDURE

5.1 The Research Office is responsible for the preparation and revision of IRB SOPs. The following format must be used when writing IRB SOPs.

5.2 SOP Format

5.2.1 Each page of the SOP will contain a header with the following information:

5.2.1.1 **TITLE:** Title of SOP.

5.2.1.2 **DOCUMENT NUMBER:** Unique number assigned to SOP. This is a sequential alphanumeric designation. Example: IRB-001.

5.2.1.2.1 **IRB** refers to the procedures related to operation and support of the IRB.

5.2.1.2.2 001 designates the sequence number of the SOP. Sequence numbers may range from 000 to 999.

5.2.1.3 **REVISION NUMBER:** Each version of the SOP will have a unique version number with the initial version designated as 00 and subsequent versions 01, 02, etc.

5.2.1.4 **SUPERSEDES/DATE:** Number and effective date of previous version.

5.2.1.5 **EFFECTIVE DATE:** Date SOP goes into effect. All approval signatures must be on the SOP as of or prior to this date.

5.2.1.6 **PAGE x OF y:** Where x is the current page of the SOP and y is the total number of pages.

5.2.1.7 Page 1 Header of the SOP also contains the printed name, signature and date of IRB Chair or designee, ACOS R&D, and Compliance designee indicating approval and date.

5.2.2 SOP Content

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5.2.2.1 Each SOP will be written with the following section headings:

5.2.2.1.1 **POLICY:** An associated institutional, legal, or safety policy that affects activities described in the SOP.

5.2.2.1.2 **DEFINITIONS:** Defines any words, acronyms, symbols, or terms that may be unfamiliar.

5.2.2.1.3 **FORMS:** Any equipment or materials needed to perform the activities described in the SOPs.

5.2.2.1.4 **REFERENCE DOCUMENTS:** Any written material referred to in the SOP such as operating manuals, publications, related SOPs, etc.

5.2.2.1.5 **PROCEDURE:** Step-by-step description of all activities to be performed in following SOP directions. A short narrative may be included in this section to further explain, provide background, or clarify procedures.

5.3 Creation of new SOPs

5.3.1 The Research Office assigns a number and title to the new SOP.

5.3.2 The Research Office drafts the SOP and distributes the draft to IRB members to review and complete a final SOP.

5.3.3 The Research Office prints the final version for signatures.

5.3.4 The Research Office distributes the original of the final SOP to each signatory.

5.3.4.1 The IRB Chair or designee's signature indicates review and agreement with the content of the SOP.

5.3.4.2 The ACOS R&D's signature indicates agreement with the content of the SOP.

5.3.4.3 The Compliance designee's signature indicates that the SOP has been reviewed for compliance with applicable regulations and guidelines.

5.3.4.4 The same individual cannot sign for approval in more than one category; an alternate signatory must be identified.

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5.3.5 Once signed/approved, the SOP is added to the IRB Standard Operating Procedure Master Log.

5.3.6 The Research Office files the original signed SOP in the master file and scans the document onto the Public (P) drive.

5.4 SOP Revision

5.4.1 Revisions to an SOP are warranted whenever procedures are changed. These revisions must occur in order to minimize deviations to the stated procedure.

5.4.2 The HRPP Coordinator revises the SOP, assigns a new revision number, and distributes the draft to the other signatories to complete a final SOP revision.

5.4.3 The Research Office prints the final version for signatures.

5.4.4 IRB Chair or designee, ACOS R&D, and Compliance sign and date the original revised SOP. Proceed with steps 5.3.4.1 - 5.3.6.

5.5 SOP Periodic Review

5.5.1 Each SOP is reviewed at least annually.

5.5.2 The Research Office maintains a review schedule.

5.5.3 The Research Office sends an SOP Scheduled Review Notice to the IRB Chair or designee, ACOS R&D, and Compliance designee indicating that the SOP is up for review and failure to respond to this notice by the assigned date will result in the SOP being removed from "ACTIVE" status to "OBSOLETE" status after this date.

5.5.4 The IRB Chair or designee, ACOS R&D, and Compliance designee respond by indicating status of SOP at least 30 days prior to SOP review notice date (e.g. obsolete, revise, no changes), sign and return the Review Notice and the SOP. If the SOP needs to be revised, proceed with section 5.4.

5.6 Distribution and Control of IRB SOPs

5.6.1 The Research Office is responsible for distribution and control of all IRB SOPs.

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5.6.2 The Research Office maintains a master file for each SOP kept in a designated secure place with access limited to Research Office personnel. The master file contains:

5.6.2.1 Original of all current, previous, and obsolete SOP versions.