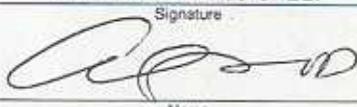
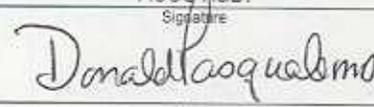


Stratton VA Medical Center IRB Standard Operating Procedure

TITLE: Record Keeping for IRB			DOCUMENT NUMBER: IRB - 007
REVISION NO.: 00	SUPERSEDES/DATE: 00	EFFECTIVE DATE: April 21, 2004	PAGE 1 OF 5

IRB CHAIR OR DESIGNEE:	ACOS R&D:	COMPLIANCE:
Signature 	Signature 	Signature 
Name Ewa Friskman	Name Donato Pasquale	Name LESA PAULSEN-CORREIS
Date 4/11/04	Date 4-15-04	Date 4-21-04-

**1 POLICY**

It is Stratton VA Medical Center's policy to comply with all applicable local, state and federal regulations in the conduct of clinical research studies. Written procedures are required to detail maintenance of adequate documentation of IRB activities.

**2 MATERIAL**

- New Protocol Submission Form
- Protocol Review Request Form for Revision/Amendment
- Request for Change in Co-investigators
- Request for Change in Principal Investigator
- Primary Reviewer Form
- Notification of Approval with Contingencies
- Expedited Review Final New Protocol Approval letter
- Full Committee Final New Protocol Approval letter
- Continuation Approval letter
- Review of Subcommittee on Human Studies (VA Form 10-1223)
- Notification of Disapproval letter
- Non-Exempt Protocol Progress Report Form
- Exempt Protocol Progress Report Form
- Expedited Review Revision/Amendment Approval letter
- Full Committee Revision/Amendment Approval letter
- New Protocol Submission Checklist
- Notification of Expiration letter
- Notification of Termination letter
- Adverse Event (AE) Reporting Form
- HIPAA Authorization

TITLE: <b>Record Keeping for IRB</b>			DOCUMENT NUMBER: <b>IRB - 007</b>
REVISION NO.: 00	SUPERSEDES/DATE: 00	EFFECTIVE DATE: 04-21-04	PAGE 2 OF 5

Waiver of HIPAA Authorization

### 3 PROCEDURE

#### 3.1 New Protocols Reviewed and Approved by the Full Committee

- 3.1.1 Before a scheduled IRB meeting, the IRB staff prepares files for new protocol submissions. Each new protocol file consists of a New Protocol Review Request Form, budget and accounting documents, and any supporting documents submitted by a Principal Investigator.
- 3.1.2 After the minutes are signed following the IRB meeting at which a new protocol was reviewed and approved, the new protocol file is placed in the *pending* file cabinet until all required modified documents have been submitted to the Research Office by the Principal Investigator.
- 3.1.3 When the Full Committee Final New Protocol Approval letter is issued, the protocol file is filed in the *active* file cabinet with a copy of the Full Committee Final New Protocol Approval letter, a copy of the original approved consent and HIPAA document(s), if applicable, scientific evaluations, if any, and any other approved supporting documents.

#### 3.2 New Protocols Reviewed and Approved under Expedited Review

- 3.2.1 IRB staff prepares files for new protocols approved under Expedited Review. Each new protocol file consists of a New Protocol Review Request Form, budget and accounting documents, and copies of all supporting documents submitted by a Principal Investigator.
- 3.2.2 When the Expedited Review Final New Protocol Approval letter is issued, the protocol file is filed in the *active* file cabinet with a copy of the Expedited Review Final New Protocol Approval letter, a copy of the original approved consent and HIPAA document(s), if applicable, and any other approved supporting documents.

#### 3.3 Revisions Reviewed and Approved by the Full Committee

- 3.3.1 After the minutes are signed following the IRB meeting at which a revision was reviewed and approved, protocol files are placed in the *pending* file cabinet until the Principal Investigator submits any required modified documents.

TITLE: <b>Record Keeping for IRB</b>			DOCUMENT NUMBER: <b>IRB - 007</b>
REVISION NO.: 00	SUPERSEDES/DATE: 00	EFFECTIVE DATE: 04-21-04	PAGE 3 OF 5

- 3.3.2 When the Full Committee Final Revision/Amendment Approval letter is issued, the protocol file is filed in the *active* file cabinet with a copy of the Full Committee Final Revision/Amendment Approval letter, the Protocol Review Request Form for Revision/Amendment, a copy of the approved revised consent and HIPAA document(s), if applicable, and any other approved documents.
- 3.4 Revisions Reviewed and Approved under Expedited Review
- 3.4.1 When the Expedited Review Revision/Amendment Approval letter is issued, a copy of the Expedited Review Revision/Amendment Approval letter with the Protocol Review Request Form for Revision/Amendment, the approved revised consent and HIPAA document(s), if applicable, and any other approved supporting documents are filed in the protocol file in the *active* file cabinets.
- 3.5 Adverse Event (AE) Reporting Forms that have been processed are filed in protocol files.
- 3.6 All reviewed correspondence between a Principal Investigator or designated contact person and the IRB is filed in the protocol file.
- 3.7 Significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, are filed in the protocol files.
- 3.8 All progress reports and any attachments received are filed in the protocol files.
- 3.8.1 If the research is approved for continuation, a Continuation Approval letter and a copy of the approved consent and HIPAA document(s), if applicable, are filed in the protocol file. If applicable, a Notification of Approval with Contingencies letter and required modified documents are also filed in the protocol file.
- 3.8.2 If the research is disapproved for continuation, a Notification of Disapproval letter is filed in the protocol file.
- 3.9 Disapproved Protocols
- 3.9.1 Files of new research disapproved by the IRB are held in the Research Office. A Notification of Disapproval letter is placed in the protocol file.

TITLE: <b>Record Keeping for IRB</b>			DOCUMENT NUMBER: <b>IRB - 007</b>
REVISION NO.: 00	SUPERSEDES/DATE: 00	EFFECTIVE DATE: 04-21-04	PAGE 4 OF 5

- 3.9.1.1 If a Principal Investigator resubmits the protocol, the modified protocol submission is filed in the original protocol file.
- 3.9.1.2 If a Principal Investigator does not resubmit the protocol within approximately 3 months, IRB staff may destroy the contents of the protocol file.
- 3.10 Terminated Protocols
- 3.10.1 When a Notification of Termination of Protocol is issued, the terminated protocol file is removed from the Research Office filing system and archived outside the Research Office in a secure location within the institution.
- 3.10.2 The VA study files shall be retained for at least 5 years, and IND study files shall be retained for 10 years.
- 3.10.3 All files involving radiation, radioisotopes, or nuclear medicine will be kept indefinitely.
- 3.11 Minutes of IRB meetings are kept in the Research Office for at least three years.
- 3.12 Educational training records are kept in the Research Office for at least 3 years.
- 3.13 A list of current IRB members is maintained on the P drive by the Research Office and is updated as changes occur.
- 3.13.1 IRB staff maintains a file of the curricula vitae of current IRB members that is updated annually.
- 3.14 A master file of each original IRB Standard Operating Procedure (SOP) is kept in the Research Office.
- 3.15 Requests for access to IRB records must be made through the Research Administration Office. Copies of IRB records will be granted only with proper approval. Each individual seeking access must document access in the IRB "Access Log to Research Office Files". The log is maintained by the HRPP Coordinator and includes the date, name, file accessed, and reason for access.
- 3.16 Records that pertain to clinical investigations regulated by the Food & Drug Administration (FDA) will be accessible for inspection and copying by authorized representatives of the FDA at reasonable times and in a reasonable manner.

Stratton VA Medical Center IRB Standard Operating Procedure

TITLE: <b>Record Keeping for IRB</b>			DOCUMENT NUMBER: <b>IRB - 007</b>
REVISION NO.: 00	SUPERSEDES/DATE: 00	EFFECTIVE DATE: 04-21-04	PAGE 5 OF 5

- 3.17 The electronic database system tracks all events related to the research, such as initial review, continuation review, AE's, as well as the documents submitted that are related to the events.