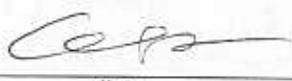
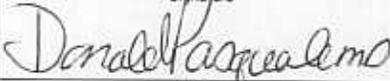
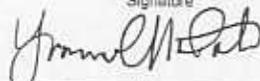


Stratton VA Medical Center IRB Standard Operating Procedure

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IRB CHAIR OR DESIGNEE: <small>Signature</small>	ACOS R&D: <small>Signature</small>	COMPLIANCE: <small>Signature</small>
		
<small>Name</small> Erika Fishman	<small>Name</small> Donald Pasqualetto	<small>Name</small> Yvonne Natche
<small>Date</small> 2/7/04	<small>Date</small> 2-12-04	<small>Date</small> 2-12-04

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 the training IRB members receive.

2 FORMS

- Human Research Protection Program Training Policy
- Station Memorandum SL-151-04: Human Studies Subcommittee
- IRB Member Policy
- Institutional Review Board Standard Operating Procedures
- The Declaration of Helsinki
- The Belmont Report
- The Nuremberg Code
- 38 CFR 16 Protection of Human Subjects
- 21 CFR 50 Protection of Human Subjects
- 21 CFR 56 Institutional Review Board
- 45 CFR 46 Protection of Human Subjects
- VHA Handbook 1200.5 Requirements for the Protection of Human Subjects in Research
- OPRR Compliance Activities: Common Findings and Guidance dated 11/29/99
- IRB Member Handbook

3 PROCEDURE

3.1 New appointed IRB Members

3.1.1 The IRB Staff contacts the new IRB member and encourages them to schedule an orientation meeting with the staff prior to attending their first IRB meeting.

3.1.1.1 The orientation will cover the following topics:

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- 3.1.1.1.1 IRB member policy (education & attendance)
- 3.1.1.1.2 Research Office contact information
- 3.1.1.1.3 IRB member roster
- 3.1.1.1.4 Use of primary reviewer form
- 3.1.1.1.5 Outline of agenda/minutes packet, MIRB database
- 3.1.2 The new IRB member is also encouraged to schedule an appointment with the IRB Chair or designee to review responsibilities as an IRB member.
- 3.1.3 The new IRB member receives a copy of the following materials:
 - 3.1.3.1 Human Research Protection Program Training Policy
 - 3.1.3.2 Station Memorandum SL-151-04: Human Studies Subcommittee
 - 3.1.3.3 IRB Member Policy
 - 3.1.3.4 Institutional Review Board Standard Operating Procedures
 - 3.1.3.5 The Declaration of Helsinki
 - 3.1.3.6 The Belmont Report
 - 3.1.3.7 38 CFR 16 Protection of Human Subjects
 - 3.1.3.8 21 CFR 50 Protection of Human Subjects
 - 3.1.3.9 21 CFR 56 Institutional Review Board
 - 3.1.3.10 45 CFR 46 Protection of Human Subjects
 - 3.1.3.11 VHA Handbook 1200.5 Requirements for the Protection of Human Subjects in Research
 - 3.1.3.12 OPRR Compliance Activities: Common Findings and Guidance dated 11/29/99
 - 3.1.3.13 IRB Member Handbook
- 3.2 All IRB members

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3.2.1 Initial Training to be completed within first 6 months of membership:

- 3.2.1.1 VA Human Studies training packet and written test. Four hours of educational credit will be issued upon successful completion of the test. A score of 80% is considered passing or the test must be retaken.
- 3.2.1.2 Health Insurance Portability and Accountability Act (HIPAA) training packet and written test. 1 hour of educational credit will be issued upon successful completion of the test. A score of 80% is considered passing or the test must be retaken.
- 3.2.1.3 Good Clinical Practice (GCP) training – completed online at http://www.va.gov/resdev/fr/stand_down/instructions.cfm
- 3.2.1.4 Informed Consent training packet and written test. 2 hours of educational credit will be issued upon successful completion of the test. A score of 80% is considered passing or the test must be retaken.

3.2.2 Continuing Education

- 3.2.2.1 At the discretion of the IRB Chair or designee, a brief education session will be held at the beginning of a scheduled IRB meeting.
- 3.2.2.2 Educational information distributed at the IRB meeting will be included in the minutes of that meeting.
- 3.2.2.3 Minutes are prepared that include:
 - 3.2.2.3.1 Attendance of IRB members at the education session and the IRB meeting.
 - 3.2.2.3.2 Educational information presented to the Committee at the meeting.
 - 3.2.2.3.3 Educational information sent to the Committee before the meeting.

3.2.3 Standard Operating Procedures (SOPs)

- 3.2.3.1 All IRB members are requested to review the IRB SOPs.
 - 3.2.3.1.1 Copies of the SOPs are available for review in the Research Office, A-603, during normal business hours.

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3.2.3.1.2 The SOPs are also available on the P drive.