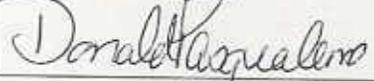
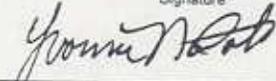


TITLE: Mandatory Training for Investigators		DOCUMENT NUMBER: IRB- 011	
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IRB CHAIR OR DESIGNEE: Signature	ACOS R&D: Signature	COMPLIANCE: Signature
		
Name Eva Fishman	Name Donald Pasquale	Name Yvonne Natale
Date 2/18/04	Date Feb-23-04	Date 2/26/04

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 for assuring that all investigators are knowledgeable about the ethical principles and regulatory requirements associated with research involving human subjects at Stratton VA Medical Center.

2 FORMS

Human Research Protection Program Training Policy
 Station Memorandum SL-151-04: Human Studies Subcommittee
 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

3 PROCEDURE

- 3.1 Principal Investigators and their research staff must complete the initial training program, and comply with continuing education requirements every calendar year, as outlined in the Human Research Protection Program Training Policy.
- 3.2 Investigators will not be allowed to initiate their research until all educational requirements are met with appropriate documentation provided to the Research Office, and Final IRB and R&D approval have been received.
- 3.3 Initial training

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- 3.3.1 The participant is provided the following items to read for initial training:
- 3.3.1.1 Human Research Protection Program Training Policy
 - 3.3.1.2 Station Memorandum SL-151-04: Human Studies Subcommittee
 - 3.3.1.3 Institutional Review Board Standard Operating Procedures
 - 3.3.1.4 The Declaration of Helsinki
 - 3.3.1.5 The Belmont Report
 - 3.3.1.6 The Nuremberg Code
 - 3.3.1.7 38 CFR 16 Protection of Human Subjects
 - 3.3.1.8 21 CFR 50 Protection of Human Subjects
 - 3.3.1.9 21 CFR 56 Institutional Review Board
 - 3.3.1.10 45 CFR 46 Protection of Human Subjects
 - 3.3.1.11 VHA Handbook 1200.5 Requirements for the Protection of Human Subjects in Research
- 3.3.2 The participant must complete and successfully pass the Initial Human Studies training test.
- 3.3.2.1 A score of 80% is considered passing or the test must be retaken.
 - 3.3.2.2 4 hours of educational credit will be issued upon successful completion of the test.
- 3.3.3 The participant must complete and successfully pass the Health Insurance Portability and Accountability Act (HIPAA) training test.
- 3.3.3.1 A score of 80% is considered passing or the test must be retaken.
 - 3.3.3.2 1 hour of educational credit will be issued upon successful completion of the test.
- 3.3.4 The participant must submit a certificate to the Research Office indicating the successful completion of Good Clinical Practice training (http://www.va.gov/resdev/fr/stand_down/instructions.cfm) or equivalent.

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- 3.4 All participants who will potentially obtain signed informed consent from research subjects are required to complete and successfully pass the Informed Consent training test.
- 3.4.1 A score of 80% is considered passing or the test must be retaken.
- 3.4.2 2 hours of educational credit will be issued upon successful completion of the test.
- 3.5 Continuing Education
- 3.5.1 The participant is required to attend at least one Human Studies training session per year provided by the Research Office.
- 3.5.1.1 The participant must complete and successfully pass a brief examination with an 80% in order to receive credit for attending the training session.
- 3.5.1.2 If the participant cannot attend one of the sessions, they are required to complete the VA component of the Collaborative IRB Training Initiative (CITI) @ <http://www.miami.edu/citireg/>
- 3.5.1.3 If the participant has not updated his or her educational training within the last 12 months, they will be required to do so at the time of continuation review.
- 3.5.1.3.1 Continuation approval will not be granted unless the continuing educational requirement is met.
- 3.5.2 The participant must submit a certificate to the Research Office indicating the successful completion of the *annual* Good Clinical Practice (GCP) training provided by the Research Office via Central Office.
- 3.6 If the participant receives less than 80% on an examination, the participant is offered the opportunity to review the incorrect answers. The participant is required to take another examination offered by the Research Office and obtain a passing grade of 80%.
- 3.7 If the participant receives less than 80% on the second examination, a remedial action plan is put in place.
- 3.7.1 The HRPP Coordinator assesses the participant's knowledge of the questions missed on the examinations and presents the information to the IRB Chair or designee and/or the ACOS R&D.

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- 3.7.2 Additional related reading materials may be assigned to the participant by the IRB Chair or designee.
- 3.7.3 Once the participant completes any additional requirements, the participant may be asked to complete another examination.
- 3.8 Educational training records are maintained in the Research Office in the database.
- 3.9 The Research Office reviews the investigator training program annually.
- 3.10 Changes to the Mandatory Training Program may be implemented at the discretion of the ACOS R&D.

Stratton V A Medical Center Albany, NY 12208
HUMAN RESEARCH PROTECTION PROGRAM TRAINING POLICY

INITIAL TRAINING - Principal Investigator(s), Co- Investigators, Sub-investigators, and Research Staff listed on the New Protocol Application Form

Upon submission of a protocol to the Research Office, new Principal Investigator(s) and their research staff directly involved with the protocol are to receive and successfully complete the following:

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.
2. Health Insurance Portability and Accountability Act (HIPAA) research 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. Good Clinical Practice (GCP) training – completed online at http://www.va.gov/resdev/fr/stand_down/instructions.cfm

Final protocol approval cannot be granted from the Institutional Review Board or the Research and Development Committee until all individuals have completed training.

INFORMED CONSENT TRAINING- Principal Investigator(s), and Research Staff who consent research participants

All Principal Investigator(s) and their research staff who will potentially obtain signed informed consent from research participants are required to receive an 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.

CONTINUING EDUCATION - Principal Investigator(s) and their Research Staff

The IRB Chair or designee will schedule two Human Studies training sessions during a calendar year. A test will accompany the sessions. It is required that Principal Investigator(s) and their research staff directly involved with a human studies protocol attend at least one of these sessions. If unable to attend either session, the Research Office requires the completion of the VA component under the Collaborative IRB Training Initiative (CITI) @ <http://www.miami.edu/citireg/>. Each individual must submit a certificate to the Research Office indicating the successful completion of the annual GCP training provided by the Research Office via Central Office.

If an individual has not updated his or her training within the last 12 months, he or she will be required to do so at the time of continuation approval or final Continuation Approval will not be granted. 1 hour of educational credit will be issued upon successful completion of the requirement.

INSTITUTIONAL REVIEW BOARD MEMBERS-

Initial Training

Institutional Review Board members are required to receive and successfully complete:

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.
2. Health Insurance Portability and Accountability Act (HIPAA) research 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. Good Clinical Practice (GCP) training – completed online at http://www.va.gov/resdev/fr/stand_down/instructions.cfm
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.

Continuing Education

The IRB Chair will present at least 6 educational topics annually at the Institutional Review Board meeting. In addition members will receive a copy of the bi-monthly publication "IRB Ethics & Human Research".

RESEARCH DEPARTMENT- ACOS, AO, IRB Staff

The Associate Chief of Staff and Administrative Officer are required to attend PRIMR (Public Responsibility in Medicine and Research) or a comparable professional conference every other year.

The Institutional Review Board (IRB) Chair or designee is required to attend PRIMR annually.

Institutional Review Board staff are required to attend PRIMR or a comparable professional conference every other year.

The ACOS, AO, IRB Chair or designee, and IRB Staff should also complete:

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.
2. Health Insurance Portability and Accountability Act (HIPAA) research 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. Good Clinical Practice (GCP) training – completed online at http://www.va.gov/resdev/fr/stand_down/instructions.cfm

Revised 1/14/04