

**Federalwide Assurance (FWA) for the Protection of Human  
Subjects for Institutions Within the United States**

**Update or Renewal for FWA Number: FWA00001281**

**1. Institution Filing Assurance**

Name of Organization: VA New Jersey Hlth Care System

City: East Orange State: NJ

HHS Institution Profile File (IPF) code, if known:

Federal Entity Identification Number (EIN), if known:

If this Assurance replaces an MPA or CPA, please provide the "M" or "T" number:

**2. Institutional Components**

List below all components over which the Institution has legal authority that operate under a different name. Also list with an asterisk (\*) any alternate names under which the Institution operates. The Institution should have available for review by the Office for Human Research Protections (OHRP) upon request a brief description and line diagram explaining the interrelationships among the Assurance Signatory Official, the Institutional Review Board(s) (IRB), IRB support staff, and investigators in these various components.

NOTE: The Signatory Official signing this Assurance must be legally authorized to represent the Institution providing this Assurance and all components listed below. Entities that the Signatory Official is not legally authorized to represent may not be listed here without the prior approval of OHRP.

<b>Name of Component or Alternate Names Used</b>	<b>City</b>	<b>State (or Country if Outside U.S.)</b>
Med Ctr	EAST ORANGE	NJ
Med Ctr	LYONS	NJ
James J. Howard (Brick) Outpatient Clinic	Brick	NJ
Elizabeth Outpatient Clinic	Elizabeth	NJ
Paterson Army Health Clinic	Fort Monmouth	NJ
Hackensack Outpatient Clinic	Hackensack	NJ
Jersey City Outpatient Clinic	Jersey City	NJ
Morristown Outpatient Clinic	Morristown	NJ
New Brunswick Outpatient Clinic	New Brunswick	NJ
Newark Outpatient Clinic	Newark	NJ

Paterson Outpatient Clinic  
Trenton Outpatient Clinic

Paterson  
Trenton

NJ  
NJ

### **3. Statement of Principles**

This Institution assures that all of its activities related to human subjects research, regardless of the source of support, will be guided by the ethical principles in the following document(s):

*The Belmont Report*

### **4. Applicability**

(a) This Institution assures that whenever it engages in human subjects research conducted or supported by any federal department or agency that has adopted the Federal Policy for the Protection of Human Subjects, known as the Common Rule, the Institution will comply with the Terms of the Federalwide Assurance for Institutions Within the United States (contained in a separate document on the OHRP website), unless the research is otherwise exempt from the requirements of the Common Rule or a department or agency conducting or supporting the research has determined that the research shall be covered by a separate assurance.

(b) Optional: This Institution elects to apply the following to all of its human subjects research regardless of the source of support, except for research that is covered by a separate assurance:

*The Common Rule (see section 3 of the Terms of the FWA for Institutions Within the United States for a list of departments and agencies that have adopted the Common Rule and the applicable citations to the Code of Federal Regulations)*

### **5. Designation of Institutional Review Boards (IRBs)**

This Institution designates the following IRB(s) for review of research under this Assurance (if the IRB has not previously registered with HHS or has not provided a membership roster to HHS, please submit to OHRP the appropriate IRB registration materials which are available on the OHRP website).

NOTE: Reliance on the IRB of another institution or organization or an independent IRB must be documented by a written agreement that is available for review by OHRP upon request. OHRP's sample IRB Authorization Agreement may be used for this purpose, or the parties involved may develop their own agreement. Future designation of other IRBs requires an update of the FWA.

<b>HHS IRB Registration Number</b>	<b>Name of IRB as Registered with HHS</b>
IRB00001450	VA New Jersey Hlth Care System IRB #1
IRB00006332	Veterans Hlth Administration Central Ofc IRB #1

**6. Human Protections Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person)**

First Name: Joselyn                      Middle Initial:                      Last Name: McLaughlin  
Degrees or Suffix: PhD                      Organizational Title: IRB Coordinator  
Institution: VA New Jersey Hlth Care System  
Telephone: 973 676-1000 3879                      FAX: 973 395-7184                      E-Mail: joselyn.mclaughlin@va.gov  
Address: 385 Tremont Ave (Mail Stop 15)  
City: East Orange                      State: NJ                      Zip Code: 07018

**7. Signatory Official (i.e., Official Legally Authorized to Represent the Institution)**

*I understand that the Assurance Training Modules on the OHRP website describe the responsibilities of the Signatory Official, the IRB Chair(s), and the Human Protections Administrator under this Assurance. Additionally, I recognize that providing research investigators, IRB members and staff, and other relevant personnel with appropriate initial and continuing education about human subject protections will help ensure that the requirements of this Assurance are satisfied.*

Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure protections for human subjects as specified above. The IRB(s) designated above are to provide review for all research to which this Assurance applies. The designated IRB(s) will comply with the Terms of the Federalwide Assurance for Institutions Within the United States and possess appropriate knowledge of the local context in which this Institution's research will be conducted.

*All information provided with this Assurance is up-to-date and accurate. I am aware that false statements could be cause for invalidating this Assurance and may lead to other administrative or legal action.*

Signature: 

Date: 8/12/09

First Name: Kenneth

Middle Initial:

Last Name: Mizrach

Degrees or Suffix: MPH

Organizational Title: Director

Institution: VA New Jersey Hlth Care System

Telephone: 973 676-1000 1211

FAX: 973 676-4226

E-Mail: kenneth.mizrach@med.va.gov

Address: 385 Tremont Ave

City: East Orange

State: NJ

NJ

Zip Code: 07018

07018

NOTE: Institutions operated by the U.S. Government may need to obtain department or agency clearance prior to submission of the FWA to OHRP. Please contact the relevant department or agency Human Subject Protections Officer before forwarding this Assurance to OHRP.

**8. FWA Approval**

The Federalwide Assurance for the Protection of Human Subjects for Institutions Within the United States submitted to HHS by the above Institution is hereby approved.

Assurance Number:

Expiration Date:

Signature of HHS Approving Official:

Date:

# VETERANS HEALTH ADMINISTRATION FACILITIES

The VA New Jersey Health Care System

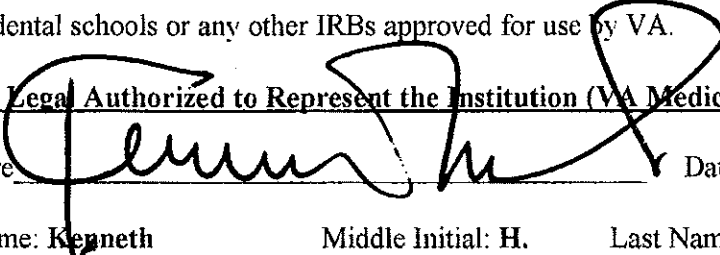
assures that all of its activities related to human subject research will comply with all requirements of Department of Veterans Affairs regulations at Title 38 Code of Federal Regulations Part 16 (38 CFR 16),

and all other applicable Department of Veterans Affairs policies and procedures, including policies and procedures of the Office of Research Oversight (ORO) and the Office of Research & Development (ORD), issued in Manuals, Handbooks and other relevant authorized Directives.

Designation on the FWA of an IRB operated by another institution requires a Memorandum of Understanding (MOU) between the institutions. VA Institutional Officials certifies on this Addendum that any MOU executed for the purpose of using an IRB operated by another institution will contain a commitment from that institution to provide complete access to all IRB records and related documents to the VA Medical Center. This commitment applies to VA-affiliated medical and dental schools or any other IRBs approved for use by VA.

(7a.) Official Legal Authorized to Represent the Institution (VA Medical Center Director):

Signature



Date:

8/25/09

First Name: **Kenneth**

Middle Initial: **H.**

Last Name: **Mizrach**

Degree or Suffix (e.g., MD, PhD) **MPH** Institutional Title: **Director, VA New Jersey Health Care System**

OHRP FWA Online Training Modules last take on: **10/8/08**

Address: **385 Tremont Avenue**

City: **East Orange**

State: **NJ**

Zip Code: **07018**

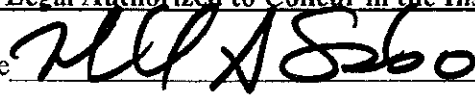
Telephone: **(973) 676-1000 ext. 1211**

FAX: **(973) 676-4226**

E-mail: **Kenneth.Mizrach@va.gov**

(7b.) Official Legal Authorized to Concur in the Institution's Approval (VHA VISN Director):

Signature



Date:

8/26/09

First Name: **Michael**

Middle Initial: **A.**

Last Name: **Sabo**

Degree or Suffix (e.g., MD, PhD)

Institutional Title: **Director, VISN #3**

OHRP FWA Online Training Modules last take on: **6/18/08**

Address: **130 West Kingsbridge Road, Building 16**

City: **Bronx**

State: **NY**

Zip Code: **10468**

Telephone: **(718) 741-4143**

FAX: **(718) 741-4141**

E-mail: **Michael.Sabo@va.gov**

**(7c.) Department of Veterans Affairs Approval**

*Section below to be completed by the Office of Research Oversight*

This Federalwide Assurance of Protection for Human Subjects is hereby approved for submission to the Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP).

Signature of VA Approving Official:



Priscilla A. Craig  
Health Science Specialist, Federalwide Assurances  
Office of Research Oversight  
Office of Research Oversight (10R)  
811 Vermont Avenue, NW, Suite 574  
Washington, DC 20420

Date: 9/8/2009

Phone: (202) 565-8162

FAX: (202) 565-9194

E-mail: priscilla.craig@va.gov

Any Additional Comments: