

## **Required Education and Training for Research Activities At The Jesse Brown VA Medical Center (JBVAMC)**

### **1. PURPOSE**

To describe the required education and training criteria for investigators and their research teams involved in research activities, R&D Committee members, VA representatives for the Collaborative IRB, and R&D Office staff dealing with human subject protection program at the Jesse Brown VA Medical Center.

### **2. POLICY**

To ensure that all investigators and their research teams who participate in research activities are properly trained to conduct studies in a compliant, safe, ethical manner.

### **3. RESPONSIBILITY**

- A. Associate Chief of Staff for Research and Development (ACOS/R&D). The ACOS/R&D is responsible for communicating education and training requirements to researchers and for making training programs available to investigators and their research teams, R&D Committee Members, R&D Office Staff, and VA Representatives for the Collaborative IRBs.
- B. Investigators are responsible for complying with training and education requirements and ensuring that all members of their research teams are properly prepared to participate in research activities.

### **4. PROCEDURES**

As of June 2003 all Principal Investigators, and their research team submitting new or continuing review research proposals or amendments to the Institutional Review Board (IRB) and the R&D Committee must provide valid training certificates in Overview of Good Clinical Practice (GCP) and the ethical principals of Human Research Subjects Protection training, VA privacy policy training and annually thereafter to the Research Office. The documentation of training must be on file in the Research Office prior to submission and review of any new proposal, continuing review or amendment. In addition, all proposals submitted to the VA Office of Research and Development (ORD) for review and funding must also include such training documentation.

Effective January 1, 2007, the Overview of Good Clinical Practice & Human Subjects courses are available through **Collaborative IRB Training Initiatives (CITI)**. The VA Office of Research & Development (ORD) will accept the completion of the CITI Group called "VA Only." Options for fulfilling VA human research training requirements are available at <http://www1.va.gov/resdev/programs/pride/training/options.cfm>. These annual training must be completed by June 15 each year (365 days). All these training courses were designed and implemented by the Central Office. These trainings are also mandatory annually for the R&D Committee members, VA representative on the Collaborative IRB, and the R&D office staff dealing with human research subject protection program.

**A. The mandatory annual trainings to protect human research subject are:**

1. CITI Course in the Protection of Human Research Subjects;
2. VHA Privacy Policy Training;
3. VA Cyber Security Awareness;
4. VA Research Data Security and Privacy (New);
5. CITI Course in the Protection of Human Subjects; Website is [ww.citiprogram.org](http://www.citiprogram.org)

a). The **NEW** combined on-line "Good Clinical Practice and Human Subjects Protection Course, "**Overview of GCP and Human Subject Protection**" is now available through CITI. This course satisfies the annual (**365 days**) training requirement for research personnel in both **Good Clinical Practice (GCP) and Human Subject Protections**. Website is [www.citiprogram.org](http://www.citiprogram.org) for GCP and Human Subject Protection VA Training.

**ALL VA Employees and NON-VA Employees must** register and complete this course on the Collaborative Training On-Line Learning website at [www.citiprogram.org](http://www.citiprogram.org).

CITI Course in the Protection of Human Research Subjects Topics is:

1. Refresher Course 101 – History and Ethics
2. Refresher Course 101 – Regulations and Process
3. Informed Consent, An Ongoing Process
4. Social and Behavioral Research
5. Record –based Research
6. Genetics Research
7. An Overview of Research with Vulnerable Subjects
8. FDA Regulation Research and Conference on Harmonization
9. Research Involving Vulnerable Adults
10. FDA regulated Research and Conference on Harmonization
11. Research Protection in the Department of VA

b) **VA Employees** are required to sign on to VA LMS website to complete the mandatory **annual** training of VHA Privacy Policy, VA Cyber Security Training and VA Research Data Security and Privacy. VA employee access:

Non-VA Computer Link: <http://www.vcampus.com/vcekpvalo/>

**c) INSTRUCTIONS FOR NON-VA EMPLOYEES FOR “VHA Privacy, VA Cyber Security, and VA Research Data Security and Privacy” MANDATORY TRAINING WEBSITES**

Non-VA employee access: go to this page and self enroll:

<https://www.vcampus.com/vcekpvalo/servlet/ekp?TX=SELFREGISTRATION>

**Finding the course through the VALO System:**

This process is the same for both VA and Non-VA employees. Once in VALO, do the following:

1. Click the Catalog link in the Knowledge Tool Box on the right of the home page.
2. Click on the Mandatory Training Catalog to see a list of the VA provided courses on the left.
3. Click on the “VHA Privacy or VA Cyberspace
4. Click the Enrollment button until you get to the Current Learning Modules page. You will see the course listed on that page.

**Printing the Course Certificate of Completion:**

Immediately after the course is completed, you can print a certificate of completion. However, if you ever need another copy or would like to see all the courses you have completed, you can access the records 24 hours after completing the course on the VALO “Records/Transcripts” page.

Your training records can be accessed by following these steps:

1. Click on the “My Courses” tab on the upper left of the main page.
2. Click on the “Records/Transcript” link

**PLEASE REMEMBER YOUR USERNAME AND PASSWORD**

**Once you print your certificate, please fax to Carol Lane at (312) 569-8114. And as always, if you have any questions or concerns, please feel free to contact Carol Lane.**

B. Non-VA employee access:

<https://www.vcampus.com/vcekpvalo/servlet/ekp?TX=SELFREGISTRATION>

### **Printing the Course Certificate of Completion**

Immediately after the course is completed, investigator can print a certificate of completion. The component of this course is as follows:

Module 1 – Sensitive VA Research Information

Module 2- Privacy of Subjects & Confidentiality of VA Research data

Module 3 – Obtaining and using VA Research data

Module 4- Storage and Security of VA Research Data

Module 5- safeguarding VA Research Data Outside the VA

Module 6 – Role and Responsibility for VA Research Data and Privacy

5. The Principal Investigator must complete “Scope of individuals Work” form for all personnel working with human subjects’ research protocol.
6. The process for handling noncompliance by investigators and other research personnel is described in the UIC OPRS policy and procedure, *Operating and Coordinating Procedures for the Administration of the Collaborative JBVAMC/NU/UIC IRB (UIC IRB #4)*..

## SCOPE OF INDIVIDUAL'S WORK

Date: \_\_\_\_\_

Protocol #: \_\_\_\_\_

**\*Please use one sheet for each person working with human subjects and make multiple copies.** Return or fax to: Doreene Wierzgacz at (312) 569-8114, R&D Office, Jesse Brown VAMC (LS CBOC) no later than **JUNE 1, 2008.**

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Individual's Name \_\_\_\_\_

### Role on Research Protocol

- |   |  |
|---|--|
| <input type="checkbox"/> Consenting patients                            | <input type="checkbox"/> Talk with patients or subjects  |
| <input type="checkbox"/> Drawing blood                                  | <input type="checkbox"/> Reviews medical records   |
| <input type="checkbox"/> Works with Patient-specific Information        | <input type="checkbox"/> Administers non-medication patient treatment or therapy               |
| <input type="checkbox"/> Administer medications to patients or subjects | <input type="checkbox"/> Performs diagnostic or therapeutic procedures on patients or subjects |
| <input type="checkbox"/> Other, please explain below                    |  |

Training certification must be dated within last 12 months and licensure must extend for next 12 months unless otherwise noted.

- Proof of license checked by principal investigator       License not applicable  
Expiration date of license: \_\_\_\_\_

- License expires in less than 12 months

- Date completed the VA annual web-based training "**Overview of GCP and Human Subject Protection**" (Please attach a copy of training certificate)

\_\_\_\_\_

- Date completed the VA annual **HIPPA training** (Please attach a copy of training certificate) \_\_\_\_\_

- Date completed the VA annual **VA Cyberspace training** (Please attach a copy of training certificate) \_\_\_\_\_

\_\_\_\_\_  
Principal Investigator's Name

\_\_\_\_\_  
Principal Investigator's Signature

B. Animal Care and Welfare Training is required for staff involved in animal research protocols "Working with the VA IACUC" <http://www.researchtraining.org/>

C. Research (Laboratory) Safety Training is required for all staff involved in laboratory-related activities; the type and extent of this training will be evaluated and provided by the facility Safety Officer; this training must be renewed on an annual basis.

D. Radiation Safety Training is required for all research staff whose duties will involve using radio-isotopes in laboratory space; the type and extent of this training will be evaluated and provided by the Radiation Safety Officer; this training must be renewed on an annual basis.