

Human Subjects Research Education Series For Investigators and Coordinators Course Schedule and Information 2009-2010

For 2009-2010, the Research Office has made some improvements to the Education Program for investigators and coordinators. Investigators and Coordinators will now have a variety of options available to them in order to fulfill their education requirements:

- **Option 1: One-hour sessions** . Very similar to the education series courses of the past, these sessions will focus on a particular regulatory area or topic related to Human Subjects Research. Sessions will be approximately 1 hour in length and the format will vary upon the topic and the speaker. In general, sessions will include approximately 10-15 minutes of overview, 15-30 minutes of instruction (which may include lecture, small group interaction, or other methods of learning), and 15-20 minutes of questions and answers. Focused sessions will be offered September thru June of each year. Each session counts toward 1.0 Education Credit. Course descriptions are available [here](#).
- **Option 2: Special Topics**. These sessions will focus on particular areas which warrant more time/discussion. Sessions will be approximately 2 hours in total length and will include lecture, small group interaction, or other methods of learning, as well as time for questions and answers. These sessions will be offered approximately once per quarter. Each session counts toward 2.0 Education Credits. Course descriptions are available [here](#)
- **Option 3: Tutorials**. A series of twelve, 10-minute PowerPoint presentations which focus on a variety of topics will be made available online. Investigators and coordinators wishing to earn education credit for completing a tutorial will be required to successfully complete a quiz (obtaining 80% or better). Each tutorial equates to 0.25 education credits. Credit for completion of each tutorial and quiz will only be granted once per calendar year. **NOTE: THIS OPTION WILL BE AVAILABLE BEGINNING IN SEPTEMBER 2009.** Sample descriptions are available [here](#)

Q: What are the education requirements for Principal Investigators?

A: The education requirements for Principal Investigators are dependent upon the date of initial approval as well as whether or not the Principal Investigator has an identified research coordinator (as noted on the research staff form) on any active study. The specific requirements are outlined in the table below:

Date of Initial Approval:	Identified Research Coordinator	No identified Research Coordinator
Prior to December 31, 2009	Minimum of four education credits	Minimum of eight education credits
Between January 1, 2010 and March 1, 2010	Minimum of two education credits	Minimum of 4 education credits
After March 1, 2010	No education requirement for the 2009-2010. Educational requirements will begin in July 2010.	No education requirement for 2009-2010. Educational requirements will begin in June 2010.

Q: What are the education requirements for Research Coordinators?

A: The education requirements for Study Coordinators are dependent upon the date of initial approval as well. The specific requirements are outlined in the table below. Note: For Research Office purposes the study coordinator must be identified as such on the Research Staff Form:

Date of Initial Approval:	Requirement
Prior to December 31, 2009	Minimum of eight education credits
Between January 1, 2010 and March 1, 2010	Minimum of 4 education credits
After March 1, 2010	No education requirement for 2009-2010. Educational requirements will begin in June 2010.

How long do I have to obtain the required education credits?

A: Education credits must be obtained between June 1st and May 31st.

Q: When and where are the one-hour sessions held?

A: The schedule of educational courses is available [here](#)

Q: Will Continuing Medical Education (CME) credits be available?

A: One CME will be available for each of the one-hour education sessions. The Research Office is working with the education office to make additional continuing education credits available. Updates will be provided as soon as new information is available.

Course Schedule for One-Hour Sessions

Sessions will be held the 2nd Monday of each month from 12:00 – 1:00 pm at University Drive (Conference Room B-1st floor near Starbucks) and the 4th Wednesday of each month from 1:00 – 2:00 pm at Highland Drive (MIRECC Conference Room- Building 4) unless otherwise noted below. Click on the session name for a course description.

<u>Month</u>	<u>Session Title</u>
September 2009	<u>Conducting Multicenter Trials</u>
October 2009 <i>Due to the Columbus Day holiday, the session at University Drive will be held on Monday, October 19th</i>	<u>Unanticipated Problems and Adverse Event Reporting</u>
November 2009 <i>Due to the Thanksgiving holiday, the session at Highland Drive, will be held on Wednesday, November 18th</i>	<u>Exempt and Expedited Research</u>
December 2009 <i>Due to the Christmas holiday, the session at Highland Drive will be held on Wednesday, December 16th</i>	<u>Research with Investigational Drugs and Devices</u>
January 2010	<u>Recruitment Strategies</u>
February 2010	<u>Informed Consent</u>
March 2010	<u>Guest Speaker</u>
April 2010	<u>The Compliance Program</u>
May 2010	<u>Research with Vulnerable Populations</u>
June 2010	<u>Research Involving Human Biological Specimens</u>

Course Descriptions

1 hour sessions (1.0 credit each)

Recruitment Strategies

Description: This session will present a variety of options that may be used to recruit and/or refer potential research subjects. Attention will be directed to those activities which are approved by the VAPHS IRB. In addition, the requirements of the Health Information Portability and Accountability Act (HIPAA) as related to recruitment will be discussed. Time will be devoted to the appropriate use of waivers, screening consents, research registries and other methods used to screen potential subjects.

Informed Consent

Description: Session will focus on the regulatory requirements related to informed consent as well as situations under which a waiver of documentation of informed consent and/or a waiver of informed consent are appropriate. Issues relating to the informed consent process will be reviewed including who is authorized to administer informed consent and where informed consent should be obtained. The VAPHS Informed Consent Template will be reviewed, as will VHA and local requirements related to the format and structure of the informed consent document. Case studies will be reviewed for group discussion.

Research with Vulnerable Populations

Description: This session will focus on the legal and regulatory requirements related to conducting VA research with vulnerable populations, such as pregnant women, children, prisoners, those with impaired decision making and those deemed incompetent to give consent. Time will be dedicated to not only reviewing the regulatory requirements, but also to local submission requirements as well

Conducting Multicenter Trials

Description: This session will focus on VAPHS IRB requirements for researchers participating in multicenter trials either as a participating site or as a coordinating site. Time will be devoted to reviewing the various forms required as part of initial submissions, continuing reviews, amendments and in the case of adverse events and unanticipated problems.

The Compliance Program

Description: The VAPHS Research Compliance Officer will provide an overview of the VAPHS Compliance Program including the requirements for Informed Consent Auditing and Regulatory Audits. Attendees will be provided with information regarding common mistakes and problems identified during audits and will be given useful tips and tools to help facilitate the auditing process. In addition, attendees will be given information regarding the Research Compliance Committee and the appropriate methods for responding to RCC requests will be discussed.

Research with Investigational Drugs and Devices

Description: Attendees will be provided with an overview of the FDA's IND and IDE regulations with a particular focus on what the VAPHS IRB will be requiring in research involving investigational drugs or devices. Particular attention will be directed to those situations in which an IND or IDE must be submitted to the FDA vs. when it meets the criteria for exemption and non-significant risk device studies. Some time will also be devoted to defining the responsibilities of the investigator in those studies in which the investigator serves as the sponsor of the study as well

Guest Speaker

Description: Each year, the VAPHS invites a guest speaker to present one session on a topic of interest to investigators and research staff. The Guest Speaker session is presented only once and will be announced in January.

Unanticipated Problem and Adverse Event Reporting

Description: This session will focus on the VAPHS IRB reporting requirements for unanticipated problems and adverse events. Case reports will be provided for group discussion.

Research involving Human Biological Specimens

Description: This session will review VA and local requirements related to working with human biological specimens as well as issues related to tissue banking, ownership and custodianship of such samples.

Exempt and Expedited Research

Description: This session will focus on the process used by the IRB to determine when research must undergo review by the convened IRB, when it meets exempt criteria, and when it is exempt from IRB review. The session will also focus on the submission process for expedited and exempt reviews. Case studies will be provided for group discussion.

Special Topics (2.0 credits each)

What Happens After My Project is Approved: Continuing Reviews, Amendments and Other Reporting Requirements

Description: This session will explore the requirements for submitting continuing reviews, amendments, study closure and other miscellaneous documents to the IRB post study approval. The session will include taking a look at the required documents and reviewing common mistakes made during the submission process. The course will also focus on proper procedures for responding to IRB comments.

Navigating the VAPHS Research Data Security and Privacy Policy Requirements

Description: This session will carefully tease apart the VAPHS Research Data Security and Privacy Policy including requirements related to education, off-site storage/transfer, methods of securing VAPHS research data, and appropriate methods for data destruction. Topics such as Business Associate Agreements and Data Use Agreements will also be discussed. Attendees will be required to participate in small group exercises. The VAPHS Information Security Officer and Privacy Officer will serve as co-speakers and will provide advice on issues related to this topic.

Conducting Research at the VAPHS: A Refresher Course for Investigators and Coordinators

Description: This course reviews the basic nuts and bolts regarding human subjects research and serves as a refresher to seasoned investigators and coordinators. Topics will include initial submission requirements and the review process, principal investigator responsibilities, resources within the VAPHS Research Office, informed consent requirements, and ways to avoid having your protocol tabled by the IRB.

Tutorial Topics (0.25 credit each): NOTE THIS OPTION WILL BE AVAILABLE IN SEPTEMBER 2009

Waivers of Informed Consent and Documentation of Informed Consent

Reviews the requirements for the two types of waivers as well as circumstances under which either or both can be used.

Unanticipated Problems

Reviews VAPHS requirements for the reporting of unanticipated problems. Also highlights the difference between unanticipated problems and exceptions.

Adverse Event Reporting

Reviews VAPHS requirements for the reporting of adverse events.

Do I need an IND?

Reviews FDA requirements for INDs and what qualifies as exempt from IND requirements.

Is my project exempt?

Reviews the requirements for exempt studies.

Can my project be expedited?

Reviews the requirements for expedited studies

Research involving employees

Reviews VA requirements for research involving employees.

Requesting Off-Site Storage/Transfer of Research Data

Summarizes the process for requesting off-site storage/transfer of research data.

HIPAA

Highlights Health Insurance Portability and Accountability Act (HIPAA) requirements related to research.

Presenting Research Results

Reviews VA requirements for presenting research results.

Quality Assurance/Quality Improvement

Provides a basic overview of QA/QI projects versus those projects that meet the definition.

My Project's Been Approved, Now What?

Summarizes a variety of topics that are both useful and necessary to the conduct of approved research at VAPHS. Topics include the use of the informational brochure "Volunteering in Research", requirements for sponsor monitoring visits, stamped informed consent documents, answering service, etc.