VA IRB Human Subjects Research Education Policy

1) All individuals involved in conducting VA human research are required to successfully complete training in accepted good clinical practices (GCP) and in the ethical principles, including courses at academic affiliates, and all other applicable VA and VHA training requirements at the local and national level. Training is required before the individual participates in VA human research.

2) This training requirement applies to all individuals involved in the conduct of VA human subjects research including investigators; study coordinators; research assistants; other members of the research team; trainees such as house officers and students; including anyone who has contact with subjects; VA IRB voting and ex officio, nonvoting members and IRB staff; VA representatives to external IRBs (e.g., affiliated academic institutions); R&D Committee members - voting and ex officio and nonvoting members; and members of other research committees or subcommittees that review research involving human subjects and all members of the research office whose responsibilities include involvement with human research.

3) This training requirement also applies to investigators and research team members conducting studies involving human subjects that are exempt from IRB review, as well as those conducting human research for which the IRB has granted a waiver of informed consent or a waiver of documentation of informed consent.

VA CITI TRAINING ACTION PLAN

a) The VA IRB Coordinators will send CITI training reminder messages to all VA human research staff with expired training. Messages sent to research study team members will be copied to their linked principal investigators. The CITI Program website will continue to send reminder e-mails 30 days prior to expiration and in the week that training expires.

b) VA human research staff must stop ALL human subjects research on the day their CITI training is expired. The study team member and their PI(s) must send a reply indicating they will comply with the work-stop order.

->When the research study team member submits an updated CITI Training Certificate to the VA IRB Coordinators, the work-stop order will be lifted.

c) Principal Investigators must stop ALL human subjects research on all of their projects on the day their CITI training is expired. The VA ACOS and VA IRB Chair will be notified of this AUTOMATIC SUSPENSION OF ALL THE INVESTIGATOR'S RESEARCH STUDIES.

->If there are patient safety concerns associated with stopping the research, the PI should submit a request to the VA IRB Chair requesting permission to continue research.

->When the PI submits an updated CITI Training Certificate to the VA IRB Coordinators, the VA ACOS and VA IRB Chair will be notified. The VA IRB Chair may approve resumption of studies or may extend the suspension until the next IRB meeting.

PRIMARY COURSE CHOICE

CITI - Good Research Practices for Protection of Human Subjects"

In collaboration with CITI, VA ORD is now sponsoring a CITI curriculum group that satisfies the **VHA triennial training requirement** for both "Good Clinical Practice" and "Ethical Principles of Human Research."

The VA IRB requires all study team members to complete CITI Training every 3 years.

1. Web-Link = https://www.citiprogram.org/default.asp
2. Select Your Institution: VA Ann Arbor, MI-506

To obtain credit for the course, you must submit a dated certificate to the Ann Arbor VA Research Office
FAX = 734-761-7693 VA Mail = 151 UM Mail = Zip 2399 US Mail = 2215 Fuller Rd

Mandatory Education (everyone must complete)

****Combined VA Privacy and Information Security Awareness and Rules of Behavior****

****VHA Privacy and HIPAA Training*****

****Infection Control: Bloodborne Pathogens & Tuberculosis Training****

https://www.tms.va.gov/plateau/user/login.jsp [VA employees and non-VA employees]