

## CREDENTIALS AND EDUCATION OF EMPLOYEES INVOLVED IN HUMAN SUBJECTS RESEARCH

1. **PURPOSE:** To establish policy for training and credentialing or otherwise validating the qualifications of employees involved in human subjects research.
2. **POLICY:** It is VHA policy that all employees involved in human subjects research, regardless of appointment mechanism (Title 38, Title 5, or Without Compensation (WOC)), must possess adequate credentials and training to ensure their understanding of the protection of human subjects and the ethical conduct of research.
3. **DEFINITION:** The following definitions apply throughout this Policy:
  - a. **Human Subject Protection (HSP) Credentialing:** HSP Credentialing is the formal, systematic process of verifying, screening and evaluating qualifications and other credentials that include formal (required) education, licensure, registration, certification, relevant training and experience and current competence.
  - b. **Human Subject Protection (HSP) Education:** The HSP Education requirements include two components: general protection of human research subjects and good clinical practices.
  - c. **Study Staff:** Study staff include: Principal Investigators, Responsible Investigators, Co-Principal Investigators, Co-Investigators, Study Coordinators and those who interact with patients in person and/or on the telephone and those who collect and analyze individually identifiable data. This applies regardless of pay status, appointment type, and length of time in the VA facility and includes research staff with a WOC appointment.
  - d. **Scope of Practice:** A Scope of Practice outlines all the duties of employees involved in human studies research that are authorized by the Principal Investigator (PI) related to his/her research study. It outlines the duties a research team member is authorized to perform during the conduct of a research study. These duties must be: 1) consistent with the occupational category under which they are hired, 2) allowed by the license, registration, or certification they hold, 3) consistent with their qualifications (education and training), and 4) agreed upon by the person's Principal Investigator and the Associate Chief of Staff for Research and Development (ACOS/R&D). Note: If an individual works on more than one research study, his/her scope of practice covers all studies. Therefore, when working on specific research protocols, the Principal Investigator for each protocol must also agree. The scope of practice statement is reviewed every two years.

#### 4. RESPONSIBILITIES:

a. **Associate Chief of Staff for Research and Development (ACOS/R&D)** is responsible for ensuring that:

(1) Individuals involved in human subjects research receive appropriate initial and annual training in the ethical principles and good clinical practices for human subjects research. The training requirement applies to all individuals, other than secretarial support, involved in human subjects research (e.g., Medical Center Director, Chief of Staff, ACOS/R&D, investigators, research coordinators and assistants, study staff, members of the R&D Committee and members and staff of the Institutional Review Board (IRB)). The HSP education will consist of a web-based course as determined by VA Office of Research and Development.

(2) Individuals involved in human subjects research have appropriate VA appointments, have been credentialed or had their qualifications validated; and that licenses of individuals in position requiring licensure are verified as current through VetPro.

(3) Individuals have a Scope of Practice or Functional Statement that is consistent with their education, licensure, or certification.

The ACOS/R&D will recommend or take disciplinary action against employees who fail to comply with the provisions of this policy

b. **Principal investigators** involved in human subjects research are responsible for ensuring that all employees under their supervision, working on approved human subjects research:

(1) Have completed required HSP Education in the ethical principles and acceptable human subjects research practices on an annual basis.

(2) Have completed required HSP credentialing process.

(3) Have approved research scope of practice statements or clinical privileges that are consistent with the employees' qualifications and that employees are working within their Scope of Practice or Functional Statement.

c. **Medical Research Service HSP Credentialing Coordinator** is responsible for providing management of the documentation and processing of individual employees including:

(1) Verification of formal education

(2) Initiation of VA appointments

(3) Documentation that individuals have been checked against required exclusionary lists (Department of Health and Human Services, and FDA Debarment List).

(4) On-going verification of employee licenses and other qualifications.

d. **Employees Involved in Human Subjects Research** are responsible for:

(1) Knowing and adhering to the research scope of practice or clinical privileges that have been approved for them.

(2) Knowing and adhering to applicable statues, regulations and policies related to conducting human subjects research.

(3) Completing required HSP education in the ethical principles and acceptable human subjects research practices on an annual basis.

(4) Engaging only in human subjects research activities that have been approved as required by VA regulations and policies.

5. REFERENCE: VHA Directive 2003-036, VHA Directive 2006-067.

6. RESCISSION: Medical Center Policy 151-009 dated March 3, 2004

7. REVIEW: The review date for this policy is June 12, 2010

8. FOLLOW UP RESPONSIBILITY: ACOS/R&D

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