

Department of Veterans Affairs  
Harry S. Truman Memorial Veterans' Hospital  
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Credentialing of Individuals Involved in Human Subjects Research

1. **PURPOSE:** To describe the process and procedures regarding the credentialing of research personnel at the Harry S. Truman Memorial Veterans' Hospital (HSTMVH).
2. **POLICY:** To require that all employees involved in human subjects research (Title 38, Title 5, or Without Compensation [WOC]) possess adequate credentials and training to ensure thorough understanding of the protection of human subjects and the ethical conduct of research.
3. **BACKGROUND:** The Department of Veterans Affairs (VA) is guided by ethical principles set forth in the Common Rule, Food and Drug Administration (FDA) regulations, and the Belmont Report. With the increased complexity of research and the advent of new technologies, all Veterans Health Administration (VHA) personnel involved in human subjects research must demonstrate and maintain the appropriate education, training, and experience to provide the highest level of protection to human subjects.
4. **DEFINITIONS:**
  - a. Background Investigation. This term refers to the investigation of the applicant's past history to a degree that is commensurate with the risk level assigned to the employee's Functional Statement of Research Duties and Responsibilities.
  - b. Belmont Report. This term refers to the "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" developed by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research on April 18, 1979.
  - c. Common Rule. This term refers to a common set of regulations governing human subjects research which are codified at Title 38 Code of Federal Regulations (CFR) Part 16.
  - d. Credentialing. Credentialing is the formal, systematic process of verifying, screening, and evaluating qualifications and other credentials that include education, licensure, relevant training, experience, and competence.
5. **PROCEDURES:**
  - a. Credentialing and validation of qualifications applies to all members of the research team (except administrative staff) and includes the following:
    - (1) Research staff who interact with patients via telephone.
    - (2) Research staff who collect and analyze laboratory specimens or data.
    - (3) Research staff who perform laboratory tests and work with data.

- (4) Research staff with a Without Compensation (WOC) appointment.
- b. Credentialing and validation of qualifications are not required for the following:
- (1) Research staff who are based at an affiliate or other outside institution and who will not access VA patients/data or access VA space for research activities.
- (2) Outside biostatisticians.
- (3) Outside laboratory technicians.
- (4) Community volunteers who represent the VA on an Institutional Review Board or the Research & Development (R&D) Committee.
- (5) Participants in data safety monitoring boards who are recruited from non-VA institutions.
- (6) Clinical personnel who periodically perform tests on research patients as part of their routine duties.
- c. Individuals involved in human subjects research will receive appropriate training in the ethical principals and good clinical practices for human subjects research on an annual basis.
- d. All employees involved in human subjects research will have appropriate background investigations; Human Resources personnel will oversee the background investigation procedures.
- e. All employees involved in human subjects research will be credentialed and have relevant qualifications appropriately validated, including licensure and educational verifications from primary sources.
- f. All employees involved in human subjects research will have approved clinical privileges or functional statements of research duties and responsibilities that are consistent with their assigned activities. Specifically, Licensed Independent Practitioners (LIPs) will be credentialed through the VetPro procedures within the Chief of Staff's Office. Non-LIP research staff will be credentialed through the Research Office. Professional licenses will be confirmed annually.
- g. Employees involved in human research will undergo employment screening via the List of Excluded Individuals and Entities (maintained by the Department of Health and Human Services) and the Debarment List (maintained by the Food and Drug Administration).
- h. Re-credentialing will be required every two years.
- i. Employees involved in human subjects research are responsible for knowing and adhering to the scope of practice or clinical privileges that have been approved for them.
- j. Employees involved in human subjects research are responsible for knowing and adhering to the applicable statutes, regulations, and policies related to the conduct of human subjects research.

k. Employees involved in human subjects research are responsible for completing required training in the ethical principles and acceptable human research practices on an annual basis.

l. Employees involved in human subjects research are responsible for engaging only in human subjects research activities that have been approved, as required by VA regulations and policies, by the R&D Committee.

6. **RESCISSION:** None.

7. **REFERENCES:**

- a. Title 21 Code of Federal Regulations (CFR) Parts 50, 56, 312, and 812
- b. Title 38 USC Section 7304
- c. Title 38, CFR Part 16
- d. VA Handbook 5005, Staffing, Part II, Chapter 3, Section B
- e. VA Handbook 0710
- f. VA Handbook 1100.19
- g. VHA Manual M-3, Part I, Chapters 2, 3, and 9
- h. VHA Directive 1200.5 "Requirements for the Protection of Human Subjects Research"

APPROVED:

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