

ELEMENT I.1.E.: The organization has an education program that contributes to the improvement of the qualifications and expertise of individuals responsible for protecting the rights and welfare of research participants.

The protection of research participants is the responsibility of many individuals in an HRPP, including IRB or EC members, chairs, and staff; researchers and research staff; and the organizational official. To protect research participants these individuals need to understand and be able to apply several areas of knowledge, including ethical principles, professional standards, organizational policies and procedures, and laws, regulations, codes, and guidance.

The depth of knowledge and skill required depends on each individual's specific task and role. For example, IRB or EC chairs or reviewers designated to use the expedited procedure for review should have more knowledge and skill than a new IRB or EC member. Researchers need different skills depending on the nature of their research or the expertise of their support staff.

An organization should have a process to ensure that individuals involved with human research protection have appropriate knowledge and skills. Such a process can include formal training and evaluation of previous training and experience. The size and breadth of the education program should be customized to meet the needs of the organization.

An organization should periodically evaluate the knowledge and skills of individuals involved in the HRPP.

Regulatory and guidance references

- **DoD:** Instruction 3216.02 5 paragraph 1.f.; 3216.02 6 paragraph 5.a-d. SECNAVINST 3900.39D paragraph. 6a(2), Minimum Education Requirements for DoD Personnel Involved in Human Research Protection Guidance (August 16, 2012)
- **VA:** VHA Directive 1200.05(3) sections 8, 26; 1200.01(3) sections 12, 14

Required written materials

1. Essential requirements:

1. The organization maintains a list of educational activities designed to contribute to the improvement of the qualifications and expertise of individuals responsible for protecting the rights and welfare of research participants.

1. Policies and procedures specify:

1. Initial education requirements, including timeframes, for researchers and research staff; IRB or EC staff, IRB or EC chairs, and members; and others.
 2. How education requirements are monitored.
 3. Continuing education requirements and time frames.
 4. What actions the IRB or EC or the organization takes if education requirements are not fulfilled.
2. When following VA requirements:
 1. For VA facilities:
 1. All individuals involved in conducting VA human participants research are required to complete training in ethical principles which apply to research conducted on human participants as specified by ORD.
 2. The R&D Committee ensures successful completion of all relevant research-related training requirements prior to approving research.

Common types of materials that may be used to meet the element

- Lists of educational activities
- Education plans
- Education records

Outcomes

- The organization has an education program to ensure that individuals involved in the HRPP have appropriate knowledge and skills.