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.

COMMENTARY

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

- **VA**: VHA Handbook 1200.05, 29
- **DoD**: Instruction 3216.02 5 paragraph 1.f.; 3216.02 6 paragraph 5.a-d. SECNAVINST 3900.39D para. 6a(2), Minimum Education Requirements for DoD Personnel Involved in Human Research Protection Guidance (August 16, 2012)

REQUIRED WRITTEN MATERIALS

(1) Essential requirements:

(a) 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.

(i) Policies and procedures specify:

(A) Initial education requirements, including timeframes, for researchers and research staff; IRB or EC staff, IRB or EC chairs, and members; and others.

(B) How education requirements are monitored.

(C) Continuing education requirements and time frames.

(D) What actions the IRB or EC or the organization takes if education requirements are not fulfilled.

(2) When following VA requirements:

(a) Policies and procedures indicate that all individuals who are subject to VA regulations are required to complete training in the ethical principles on which human research is to be conducted before they may participate in human participants research in accordance with requirements specified by ORD; the local site can require additional training.

REQUIRED WRITTEN MATERIALS

(3) When following DoD requirements:

(a) Policies and procedures require initial and continuing research ethics education for all personnel who conduct, review, approve, oversee, support, or manage human participants research.

(i) There might be specific DoD educational requirements or certification required by different DoD components.

(ii) The DoD component may evaluate the education policies to ensure the personnel are qualified to perform the research, based on the complexity and risk of the research.

(b) Policies and procedures indicate how the IRB or EC staff, chair, and members; and researchers and research staff become aware of the specific requirements contained in DoD regulations and requirements and educated about these requirements when appropriate.

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.

STANDARD III-2 Researchers meet requirements for conducting research with participants and comply with all applicable laws, regulations, codes, and guidance; the organization's policies and procedures for protecting research participants; and the IRB's or EC's determinations.

ELEMENT III.2.A. Researchers and research staff are qualified by training and experience for their research roles, including knowledge of applicable laws, regulations, codes, and guidance; relevant professional standards; and the organization's policies and procedures regarding the protection of research participants.

COMMENTARY

Researchers and research staff should be qualified by training and experience for their roles and responsibilities in conducting research so that they follow the protocol and abide by the organization's policies and procedures. Researchers and research staff should have the knowledge to follow laws, regulations, codes, and guidance such as those concerning IRB or EC review, consent requirements, reporting requirements, maintenance of records, retention of records, and supervision of research conduct. When appropriate, Researchers and research staff should understand and apply relevant professional standards that are applicable to their research.

See AAHRPP Tip Sheet 11
See AAHRPP Tip Sheet 18

REGULATORY AND GUIDANCE REFERENCES

- **DHHS**: 45 CFR 46.102(d), 45 CFR 46.102 (f)
- **FDA**: 21 CFR 50.3(a), 21 CFR 50.3(c), 21 CFR 50.3(g), 21 CFR 50.3(j), 21 CFR 56.102(c), 21 CFR 56.102(l)
- **VA**: 38 CFR 16.102(d), 38 CFR 16.102 (f), ICH-GCP: 2.7, 2.8, 4.1.1 – 4.1.4, 4.3.1, 4.3.2, 4.4.1 – 4.4.3, 4.5.1 – 4.5.4, 4.6.1 – 4.6.6, 4.7, 4.9.1-4.9.5
- **DOJ**: 28 CFR 512.11 (a)(6)

REQUIRED WRITTEN MATERIALS

(1) Essential requirements:

(a) Policies and procedures pertaining to Element I.1.D. that address essential requirements. If the same policies and procedures are provided to researchers and research staff, simply reference those documents in the application for this Element. If there are additional materials, such as an Investigator Handbook or Web pages for researchers, that are not included in the materials used to support Element I.1.D, but are in support of Element III.2.A., include them here.

(2) When following the ICH-GCP (E6) guideline:

(a) Policies and procedures describe that the researcher and research staff are knowledgeable about the following responsibilities:

(b) The researcher provides evidence of his or her qualifications through up-to-date curriculum vitae or other relevant documentation requested by the sponsor, the IRB or EC, or the regulatory authority.

(c) The researcher is familiar with the appropriate use of the investigational product, as described in the protocol, in the current investigator brochure, in the product information, and in other information sources provided by the sponsor.

(d) A qualified physician (or dentist, when appropriate), who is a researcher or a co-researcher for the clinical trial, is responsible for all clinical trial-related

REQUIRED WRITTEN MATERIALS

medical (or dental) decisions (not applicable to independent IRBs or ECs).

(e) During and following a participant's participation in a clinical trial, the researcher ensures that adequate medical care is provided to a participant for any adverse events, including clinically significant laboratory values, related to the clinical trial (not applicable to independent IRBs or ECs).

(f) The researcher ensures the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor.

OUTCOMES

- Researchers and research staff are qualified by training and experience for their roles and responsibilities in conducting research.
- Researchers and research staff know which laws, regulations, codes, and guidance govern their research studies and are knowledgeable about requirements pertaining to specific research studies.
- Researchers and research staff are knowledgeable about the organization's policies and procedures.