ELEMENT I.4.A.: The organization has and follows written policies and procedures that establish a safe, confidential, and reliable channel for current, prospective, or past research participants or their designated representatives that permits them to discuss problems, concerns, and questions; obtain information; or offer input with an informed individual who is unaffiliated with the specific research protocol or plan.

Organizations should provide information to current, former, and prospective research participants about whom to contact for concerns, questions, or complaints about the research; obtain information; or offer input. Organizations should also have a mechanism to solicit concerns, questions, or input from prospective participants. The organization should have policies and procedures that describe the steps followed by the organization to respond to contacts from participants or others.

Regulatory and guidance references

- **DHHS**: 45 CFR 46.116(a)(6)-(7)
- **FDA**: 21 CFR 50.25(a)(6)-(7), FDA Information Sheets: A Guide to Informed Consent
- **VA**: VHA Directive 1200.05(3) section 17

Required written materials

1. Essential requirements:
    1. Contact information for an individual or office that is unaffiliated with a specific research study is available to current, former, and prospective research participants to:
        1. Discuss problems, concerns, and questions.
        2. Obtain information.
        3. Offer input.
    2. Policies and procedures describe the steps followed when the organization responds contacts from participants or others.

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

- Web site
- Pamphlet or brochure
- Consent template

Outcomes

- The organization provides information to current, former, and prospective participants or others about whom to contact in the organization to discuss problems, concerns, and questions; obtain information; and offer input.

- The organization responds to contacts from participants or others.