

ELEMENT I.4.B. The organization conducts activities designed to enhance understanding of human research by participants, prospective participants, or their communities, when appropriate. These activities are evaluated on a regular basis for improvement.

COMMENTARY

To enhance the public's understanding of research, organizations should perform outreach activities. The scope of the outreach activities should be proportional to the size and complexity of the research program. There is no requirement that a single activity will result in measurable changes in community understanding.

REGULATORY AND GUIDANCE REFERENCES

- None

REQUIRED WRITTEN MATERIALS

(1) Essential requirements:

- (a) Policies and procedures describe the plan and methods for enhancing the understanding of participants, prospective participants, and communities.
- (b) Policies and procedures describe the periodic evaluation of outreach activities.

COMMON TYPES OF MATERIALS THAT MAY BE USED TO MEET THE ELEMENT

- Pamphlet or brochure
- Web site
- Research Day
- Mini-medical school
- Speaker bureau
- Evaluation reports
- Quality improvement plans

OUTCOMES

- The organization provides information designed to enhance the understanding of research involving participants and their community.
- IRB or EC members and researchers can describe the characteristics and culture of the communities in which they oversee or conduct research, respectively.
- The organization makes improvements to its outreach activities as needed, based upon a periodic assessment.

ELEMENT I.4.C. The organization promotes the involvement of community members, when appropriate, in the design and implementation of research and the dissemination of results.

COMMENTARY

In some instances, the design and implementation of research can be enhanced when individuals from the community in which the research will be conducted are involved in the design, conduct, and analysis of data from the research. This can occur for an individual study or group of studies. This Element is not applicable, or appropriate, for all research studies.

An organization can facilitate the involvement of community members by supporting community or patient advocacy boards, supporting researchers who wish to conduct community-based participatory research or other types of research that involve community members, or supporting the IRB or EC in developing the expertise to review community-based participatory research.

REGULATORY AND GUIDANCE REFERENCES

- None

REQUIRED WRITTEN MATERIALS

(1) Essential requirements:

- (a) Policies and procedures describe the additional considerations for reviewing research that involves community members in the research process, including:
 - (i) The design and implementation of research
 - (ii) The dissemination of results.

COMMON TYPES OF MATERIALS THAT MAY BE USED TO MEET THE ELEMENT

- Research studies using a community-based participatory research design
- Use of community advisory boards
- Use of participant advocates
- Partnerships with community-based organizations

OUTCOMES

- When appropriate, the organization supports mechanisms that allow researchers to involve community members in the research process, including the design and implementation of research and the dissemination of results.
- When appropriate, researchers involve community members in the design, conduct, and analysis of data.
- When appropriate, researchers inform community members about the results of the research study and utilize community members to help disseminate results.