

Tip Sheet 12: IRB or EC Authority and Independence

Related Accreditation Elements: I.1.C.

The Organization should grant, recognize, and maintain the independent authority of the IRB or EC.

Recommended Content:

The authority of the IRB or EC to act independently should be granted by the organizational official or body with the authority to bind the entire Organization, such as the president, chief executive officer, board of directors, or other organizational officials.

Authority of the IRB or EC:

1. Indicate that the Organization grants the IRB or EC the authority:
 - a. To approve, require modifications to secure approval, or disapprove all research activities overseen and conducted by the Organization.
 - b. To suspend or terminate approval of research not being conducted in accordance with the IRB's or EC's requirements or that has been associated with unexpected serious harm to participants.
 - c. To observe, or have a third party observe, the consent process.
 - d. To observe, or have a third party observe, the conduct of the research.
2. Indicate that officials of the Organization are not allowed to approve the research if it has not been approved by the IRB or EC.

Independence of the IRB or EC:

1. Describe to whom attempts to inappropriately influence the IRB or EC should be reported.
2. Indicate who is granted the responsibility and authority to respond to attempts to unduly influence the IRB or EC.
3. Describe the types of responses to attempts to unduly influence the IRB or EC.