

Tip Sheet 4: Evaluating the Maintenance of Confidentiality of Data in Proposed Research

Related Accreditation Element: II.3.E.

A criterion for approval of research is the presence of adequate provisions to maintain the confidentiality of identifiable data collected during a research study.

Recommended Content:

This policy and procedure may stand alone or be part of an umbrella policy and procedure addressing criteria for approval.

1. Cite or repeat the criterion for approval pertaining to confidentiality of data found in the relevant laws, regulations, codes, or guidance.
2. Evaluation of provisions to maintain the confidentiality of identifiable data collected as part of the research:
 - a. Describe the types of information addressing provisions to maintain confidentiality that Researchers are asked to provide in the research protocol or plan.
 - b. Describe the circumstances under which the IRB or EC considers provisions to maintain confidentiality to be appropriate.
 - c. When the IRB or EC reviews provisions to maintain confidentiality of data, describe the types of issues the IRB or EC should consider in evaluating whether the provisions are adequate.

Other suggestions:

1. If your IRB or EC uses a checklist, include the evaluation of provisions to maintain the confidentiality of data in the checklist or other supporting forms the IRB or EC uses.
2. Include the evaluation of the maintenance of the confidentiality of data in supporting forms for Researchers, such as an application form.