

Tip Sheet 2: Determining Whether an Activity is Research Involving Human Participants

Related Accreditation Elements: I.1.A. and III.1.A.

Organizations should have policies and procedures describing when activities meet the definitions of research involving human participants. The question of whether an activity represents research involving human participants arises when Organizations conduct, for example, quality improvement programs, public health activities, program evaluations, classroom exercises, operations activities, or innovative medical care.

Recommended Content:

Describe the criteria used to make determinations:

1. Cite or repeat the applicable laws, regulations, codes or guidance under which research determinations must be made (e.g., 45 CFR 46 (DHHS regulations), 21CFR 56 (FDA regulations), and 28 CFR 512.10 (DOJ regulations)).
2. Cite or repeat the legal or regulatory definitions pertaining to determinations (e.g., research, human participant, private information, experimental subjects, and clinical investigation).
3. Cite other organizational policies that expand on the legal or regulatory definitions of research involving human participants.
4. If your Organization follows multiple laws and regulations, define research involving human participants to encompass all applicable laws and regulations.
5. Add explanatory text to the definitions as desired.
6. If your Organization conducts activities that commonly lead to questions about whether the activities met the definitions of research, identify each class of activity and provide guidance for making research determinations for each class.

Describe the process for making determinations:

1. Indicate the entity (title of person or office) that can provide a determination.
2. Describe the criteria used to make determinations.
3. Describe the process used to communicate determinations to Researchers.
4. Indicate the time frame, if any, for making determinations and for communicating the determination to the Researcher.