Tip Sheet 9: Exemptions: Determinations and Review

Related Accreditation Elements: II.2.A.

Organizations should have policies and procedures to differentiate activities that represent research involving human participants that is exempt from laws or regulation from those that are not. This determination should consider the exemption rules of all applicable laws and regulations, as activities that are exempt from one set of laws or regulations might not be exempt under the other.

Recommended Content:

Describe the criteria used to make determinations:

1. Cite or repeat the exemption criteria from applicable laws or regulations.
2. Add explanatory text to the exemption categories as desired.
3. If your Organization follows both DHHS and FDA regulations, describe the circumstances under which DHHS exemptions can be applied to FDA-regulated research, and vice versa.
4. If your Organization conducts or oversees research involving prisoners as participants, state that federal exemptions do not apply to research involving prisoners.
5. If your Organization conducts or oversees research involving children as participants, describe the circumstances under which exemptions may be granted and the circumstances under which exemptions may not be granted.
6. Organizations may elect to restrict or not use one or more categories of exemption, and to require such research to meet all regulatory criteria for approval. If so, this should be described.
7. Describe the criteria used to determine that research that is exempt meets the ethical standards of the Organization. The criteria should be relevant to the type and nature of the research. Generally, the criteria used for a particular research prototocl or plan will be a subset of the criteria used by the convened IRB or EC. As an example,
    a. The research involves no more than minimal risk to participants.
    b. If participants will be enrolled, selection is equitable.
    c. If there is recording of identifiable information, there are adequate provisions to maintain the confidentiality of the data.
    d. If there are interactions with participants, there will be a consent process that will disclose such information as:
        i. That the activity involves research.
        ii. A description of the procedures.
        iii. That participation is voluntary.
        iv. Name and contact information for the Researcher.

e. There are adequate provisions to maintain the privacy interests of participants.

Describe the process for making the determination:

1. Identify the entity (title of person or office) that makes the determination that the research is exempt.
2. Describe the criteria used to make determinations.
3. Indicate in the record of the determination the reference to one or more categories under which the exemption is granted.
4. Describe the process to communicate determinations to the Researcher.
5. Indicate the time frame, if any, for communicating the determination to the Researcher.