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A c on M y B d A

The Code of Federal Regulations, Title 45 CFR Part 46, identifies several different categories of minimal risk research as being exempt from federal policy for the protection of human research subjects.

The IRB does not actually approve an exempt study but instead makes a determination that the project meets at least one of the federal exempt categories criteria. Therefore, annual review is not required and no expiration date will be listed on the approval letter. Exempt research does not require closure notification with the Jacksonville University IRB.

The significance of exempt status is that the research activity is not monitored by the IRB. Assuming the project does not change, it also is not subject to continuing IRB oversight. Exempt status does not, however, lessen the ethical obligations to subjects as articulated in the Belmont Report and federal regulations. Thus, investigators performing exempt studies need to protect confidentiality, minimize risks, and address problems or complaints.

Although regulations do not require informed consent for exempt research, the JU IRB has determined that some form of informed consent is ethically appropriate to ensure that prospective participants are informed of the research and have an opportunity to decide for themselves whether or not to participate. For exempt research that involves interaction with subjects, there usually should be a process to ask subjects to participate and confirm their agreement. However, signed consent is not normally required for exempt research and the consent process can be much simpler than that required for non-exempt research.

For exempt research involving minors as research subjects, written or verbal informed assent obtained from the minors is necessary and sufficient provided written informed consent is also obtained from an adult who is directly responsible for the wellbeing and safety of the minors during the time of data collection.

For verbal informed consent, the Investigator should follow the steps below:

1) The Investigator (or an IRB approved designee), must explain the study to the potential subjects verbally, providing all pertinent information, and must allow the potential subject ample opportunity to ask questions. At a minimum, the required information for verbal informed consent scripts should include:

    a) That the activity involves research and participation is voluntary.

safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Applications that do not meet the criteria for exempt review will be recommended for either an expedited review or for review by a convened IRB committee.

Application May Be Considered Expedited

The Secretary, HHS, has established, and published as a Notice in the FEDERAL REGISTER, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate, after consultation with other departments and agencies, through periodic republication by the Secretary,

procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

B. The categories in this list apply regardless of the age of subjects, except as noted.

C. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

D. The expedited review procedure may not be used for classified research involving human subjects.

E. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

F. Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
    a. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

    b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is

3. Prospective collection of biological specimens for research purposes by noninvasive means.

   Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d)

this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)