JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 9, No. 5, May 2013 "Happy Trials to You"

What's New in GCP?
SACHRP Recommends Expanding Expedited Review Categories

Reprinted from the Guide to Good Clinical Practice with permission of Thompson Publishing Group, 805 15th St., Washington, D.C. 20005; www.thompson.com. To learn more about the Guide to Good Clinical Practice, visit: www.firstclinical.com/gcpguide.

On March 13, the Secretary's Advisory Committee on Human Research Protections (SACHRP) recommended expanding the categories of research that institutional review boards (IRBs) may review using expedited review procedures. The categories were last changed in 1998.

SACHRP recommended adding categories for the establishment of subject recruitment databases and activities at statistical and data coordinating centers or biospecimen repositories that are not responsible for the primary oversight of the study and are not involved in the primary collection of data or specimens.

Under an expedited review, the IRB chair or a designated experienced IRB member reviews the research rather than having the entire convened IRB review it. The reviewer may exercise all the authorities of the IRB except disapproving the research.

To be eligible for expedited review, the research must present no more than minimal risk to human subjects and involve one or more of the expedited categories. SACHRP noted that "the categories and their examples should not be deemed to be of minimal risk simply because they are included on [the expedited] list. Inclusion on this list means only that research falling within one or more of the categories is eligible for review through the expedited review procedure when it is determined that the proposed research involves no more than minimal risk to human subjects." SACHRP added that "research that may be eligible for expedited review must fit into one of the categories but is not limited to the specific examples."

The 11 categories and examples of each proposed by SACHRP are as follows:

- Clinical studies of drugs and medical devices only when one of two conditions is met:
  - Research on drugs for which an investigational new drug application (21 C.F.R. Part 312) is not required. However, 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.
  - Research on medical devices where an investigational device exemption (IDE) application or an abbreviated IDE application for a nonsignificant risk (NSR) device (21 C.F.R. Part 812) is not required. Circumstances where an IDE would not be required include those where an NSR device is being reviewed by an IRB under 21 C.F.R. §812.2(b); or the medical device is cleared/approved for marketing and is being used in accordance with its cleared/approved labeling; or the research is exempt from the IDE submission requirements under 21 C.F.R. §812.2(c).
- The collection of blood specimens using techniques consistent with routine clinical practice to minimize pain and risk of infection and within the following limits of volume: from non-pregnant adults who weigh at least 50 kg, the amounts collected should not exceed 550 ml in an eight-week period; or from children and other adults, the amount of blood to be collected should not exceed the lesser of 150 ml or 3 ml per kg in an eight-week period. Examples:

    - Finger, heel or ear stick with reasonable limits on frequency and with volumes consistent with clinical practice employing these methods;
    - Venipuncture with reasonable limits on frequency and with the same limits;
    - Collection of blood from an in-dwelling peripheral venous catheter placed for research purposes with the same volume limits;
    - Collection of blood from an in-dwelling catheter already in place for clinical purposes, with the same volume limits.
- Prospective collection of biological specimens, excluding blood, for research purposes by noninvasive or minimally invasive means. Examples:
    - Tissues and fluids that the body produces continuously or sheds as a normal process, which are collected in a non-disfiguring manner;
    - Tissues and fluids if routine patient care indicates a need for removal or extraction;
    - Dental plaque and calculus;
    - Tissues from non-facial, non-genital, skin punch biopsies in adults that do not require sutures;
    - Specimens collected by curettage, urethral, vaginal or rectal swabs in adults;
    - Specimens collected from the external auditory canal or nares.
- Collection of additional data and biological specimens, excluding blood specimens, for research purposes during procedures already being performed for clinical purposes, provided the additional collection does not entail a minimal increase in risk, pain or discomfort. Examples:
    - Collection of additional bodily fluids (e.g., peritoneal fluid, bone marrow, or cerebrospinal fluid);
    - Reasonable extension of anesthesia, sedation or operating room time to allow collection of additional data or specimens;
    - Tissues collected from pap smears.
- Collection of data through noninvasive or minimally invasive procedures (not requiring the addition of general anesthesia or sedation for research purposes) routinely employed in clinical practice. Examples:
    - Physical sensors that are applied either to the surface of the body or at a distance;
    - Weighing or testing sensory acuity;
    - Magnetic resonance imaging;
    - Electrocardiography, electroencephalograhy, thermography, detection of naturally occurring radioactivity, electroetinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography;
    - Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing;
    - Allergy skin-testing in subjects not known or suspected to have serious allergies to the allergen being tested;
    - Procedures in adults involving a single exposure to ionizing radiation with an effective dose not exceeding 0.1 mSv (the amount typically associated with a chest x-ray), provided appropriate shielding techniques are employed.
- Secondary use of materials (data, documents, records or biological specimens) that have been or will be collected for purposes other than the currently proposed research project. Examples:
    - Secondary use of data collected from another research study, provided the use is not inconsistent with the original terms of informed consent;
    - Secondary use of clinical or education records;
    - Used banked specimens in biorepositories.
- Activities at statistical and data coordinating centers or biospecimen repositories that are not responsible for the primary oversight of the study and are not involved in the

primary collection of data or specimens, which may be ongoing at other sites. Example:
    - Multicenter clinical trial where data are gathered under separate IRB approval(s) for the performance sites, but received and managed by a central coordinating center that does not otherwise participate in the clinical intervention or interact directly with subjects.
- Collection of data from voice, video, digital or image recordings made for research purposes.
- Surveys, interviews, self-reports, direct and indirect observations of individual and group behavior, other verbal or computer-assisted interactions or assessments, non-invasive physical or behavioral tasks, manipulation of the subject's environment and similar methods commonly used in cognitive, behavioral, social, ethnographic, educational, health and epidemiologic research. Examples:
    - Measures of performance on cognitive, perceptual, neuropsychological, behavioral and other related tasks employing non-invasive technologies (e.g., paper and pencil assessment, computerized tasks, remote data collection using mobile devices);
    - Interviews, questionnaires, surveys, focus groups, and Internet-based data collection on personal experience, identity, language, relationships, attitudes, beliefs and practices;
    - Psychiatric diagnostic or symptom assessments in healthy or mentally ill populations conducted by clinicians or trained interviewers (with appropriate mechanisms for clinical back-up or referral);
    - Measures of symptoms, mobility, range of motion, quality of life and activities of daily living in patient and non-patient populations by clinical or other trained personnel (e.g., nurses, physicians, social workers);
    - Methods used in ergonomics and human factors research including cognitive, human-computer, physiological and bio-mechanical measures in consumer, industrial and biomedical settings;
    - Qualitative and quantitative data collection through observation, participant observation, and interaction with groups in naturalistic settings (including the Internet);
    - Surveys on personal and family finances, consumer preferences, and decision-making;
    - Assessments of compliance with medication or treatment regimens;
    - Surveys to establish effectiveness of public health interventions.
- Establishment of subject recruitment databases. Examples:
    - Collection of identifiable information for the purpose of establishing subject pools;
    - Disease-specific patient registries;
    - Screening protocols, including interviews, questionnaires and physical assessments that could be expedited under one of the other categories.
- Research previously approved by the convened IRB and now subject to continuing review where one of the following conditions apply:
    - The research is permanently closed to the enrollment of new subjects, all subjects have completed all research-related interventions, and the research remains active only for long-term follow-up of subjects; or
    - No subjects have been enrolled and no additional risks have been identified; or
    - The remaining research activities are limited to data analysis; or
    - A non-significant risk determination was initially made by a convened IRB for research involving medical devices and the research was determined to present no greater than minimal risk to the subject; or

- The IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk, and no additional risks have been identified.

Other Recent Developments in the Guide to Good Clinical Practice

Bioethics Panel Proposes Ethical Framework for 407/50.54 Reviews

Changes in HIPAA Bring Challenges for IRBs

Mass. Court Rejects Commercial Disparagement Claim Against Author of Article with Negative Results