

SPARROW HEALTH SYSTEM
INSTITUTIONAL RESEARCH REVIEW COMMITTEE

POLICY: EXPEDITED REVIEW

PURPOSE:

Research activities involving no more than minimal risk¹ and in which the only involvement of human subjects will be in one or more of the following categories may be reviewed by the Institutional Research Review Committee through expedited review procedure² authorized in 46 CFR § 46.110 and 21 CFR § 56.110.

APPLICABILITY:

- A. Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRRC through the expedited review procedures authorized by 45 CFR § 46.110 and 21 CFR § 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedures 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 procedures 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 not greater than minimal.
- D. The expedited review procedure may not be used for classified research involving human subjects.
- E. 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.

SPECIFIC CATEGORIES:

A research project is identified as *expedited review* if it involves no more than minimal risk and only involves human subjects (or materials of human origin) in one or more of the following categories:

1. **Clinical studies of drugs and medical devices only when** (a) research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. 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. **Or** (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 cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. **Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:**
(a) healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; **Or** (b) from adults and children³, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
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) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
4. **Collection of data through noninvasive procedures** (not involving general anesthesia or sedation) routinely employed in clinical practice, **excluding procedures involving x-rays or microwaves.** Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of

the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. **Research involving materials** (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: some research in this category may be exempt from the DHHS regulations for the protection of human subjects. 45 CFR § 46.101(b)(4) – see *Exempt policy, category #4*. This listing refers only to research that is not exempt.)
6. **Collection of data from voice, video, digital, or image recordings made for research purposes.**
7. **Research on individual or group characteristics or behavior** (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: some research in this category may be exempt from DHHS regulations for the protection of human subjects. 45 CFR § 46.101(b)(2) and (b)(3) – see *IRRC Exempt policy, category #2*. This listing refers only to research that is not exempt.)
8. **Continuing review of research previously approved by the convened IRB as follows:**
 - (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; **Or** (b) where no subjects have been enrolled and no additional risks have been identified; **Or** (c) where the remaining research activities are limited to data analysis.
9. **Continuing review of research**, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but 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. See *IRRC policy: Expedited Review of Minor Changes in a Previously Approved Study*.

¹Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. 45 CFR § 46.102(i). [Note: in the process of determining what determines risk, only those risks that may result from the research, as distinguished from those associated with therapies subjects would undergo even if not participating in research, should be considered. It is possible for the risks of the study to be minimal when the procedure itself is more than minimal.]

²An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR § 46.110.

³Children are defined in the DHHS regulations as “persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.” 45 CFR § 46.402(a)

Responsibility:

The IRB Administrator is responsible for identifying submissions that qualify for expedited review.

IRB Chair, Co-Chair, or designated reviewer, is responsible for conducting expedited review.

Authority of the IRB Chairperson:

The IRB Chair, Co-Chair, or designated reviewer, may exercise all of the authorities of the IRB, except that he/she may not disapprove the research. A research proposal may be disapproved only after review by the full IRB.

Notification of the IRB:

When the expedited review procedure is used for any review, all regular IRB members shall be informed of actions taken by the IRB Chair or designated reviewer, during the next convened meeting.

Documentation:

If the study qualifies for expedited review, the minutes will include documentation of the initial or continuing review of the protocols that were reviewed via expedited review and any issues resolved relating to questions that IRB members had concerning the protocols reviewed.

Additional Items that May be Reviewed by the Chair, Chair’s designee, or IRB Administrator

Conditional approval pending minor revisions, clarification: Specific revisions to consent documents and other documentation or clarifications submitted as a result of full IRB review and as a condition to final approval may be reviewed by the IRB Chair, the Chair’s designee, or IRB Administrator. Final approval will be

issued providing the revisions, documentation or clarifications do not indicate or result in a change to the study or change to the risk/benefit ratio.

APPLICABLE REGULATIONS AND GUIDELINES:

Minimal Risk: 45 CFR § 46.102(i)
21 CFR § 56.102(i)

Expedited Review: 45 CFR § 46.110
21 CFR § 56.110
21 CFR Parts 312 and 812
FDA Information Sheets, 1998
OHRP IRB Guidebook
Federal Register Vol. 63, No. 216

Reviewed/Revised: 01/02/95; 05/21/97; 1/98; 11/01; 1/03; 10/04
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