

 <b>JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH</b>	<b>Human Research Protection Program Policies &amp; Procedures</b>	
	Identification	Page 1 of 3
Title: <b>Review of New Applications</b>	Date Effective 11/05/04	Supercedes P&P dated 6/16/04

## **Expedited Review**

Federal regulations recognize certain kinds of research, listed below, that are not more than minimal risk and that may be reviewed by an IRB through an expedited review process. Research that qualifies for expedited review is reviewed and approved by one or more CHR members (primary reviewers) or Co-Chairs and is not presented at a convened CHR meeting. All research approved under an expedited review procedure is re-reviewed at least annually. The reviewer may approve the project or recommend revision, but may not disapprove it. The CHR Co-Chair retains the right to require full Committee review, even for projects that appear to meet the criteria for expedited review. A monthly report of all research approved through an expedited review procedure is distributed to members at the full Committee meeting.

It should be noted that expedited review does *not* mean the review occurs any more quickly than a full Committee review.

If the proposed research is on the list below, it does not automatically mean it is eligible for expedited review. If any part of the proposed research is more than minimal risk, it must be reviewed by the full Committee. Research in any of these categories is *not* eligible for expedited review if the identification of 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, or 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.

Classified research is also *not* eligible for expedited review.

Criteria that determine whether research qualifies for expedited review apply regardless of the age of the subjects, except as noted below.

Activities 1-7 below apply to both *initial and continuing* expedited reviews.

- 1) Clinical studies of drugs and devices only under the following conditions:
  - a) Research on drugs or devices for which an investigational new drug (IND) exemption is not required, but *only* if the research does not significantly increase the risks, or decrease the acceptability of the risks, associated with use of the product.

- b) Research on medical devices for which (i) an investigational device exemption (IDE) is not required (21 CFR 812), or (ii) the medical device is cleared or approved for marketing and the medical device will be used in accordance with its cleared or approved labeling.
- 2) Collection of blood samples by finger stick, heel stick, ear stick or venipuncture as follows:
- a) from healthy, non-pregnant adults, who weigh at least 110 pounds. (Amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more than 2 times per week.) or
  - b) from other adults and children, considering age, weight, and health, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. (The amount drawn may not exceed the lesser of 50 ml or 3 ml/kg in an 8-week period and may not occur more 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 non-disfiguring manner;
  - b) deciduous teeth at the time of exfoliation;
  - c) permanent teeth if patient care indicates a need for extraction;
  - d) collection of excreta and external secretions (including sweat);
  - e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or 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) collection of both supra- and subgingival dental plaque and calculus, provided the collection procedure is accomplished in accordance with accepted prophylactic techniques;
  - i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; and
  - 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 or approved for marketing. 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, echography, ultrasound, infrared imaging, doppler blood flow, and echocardiography; and
  - 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).
  - 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.
  - 8) Continuing review of research previously approved by the convened IRB as follows:
    - a) the research is (i) permanently closed to the enrollment of new subjects, and (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) no subjects have been enrolled and no additional risks have been identified; or
    - c) the remaining research activities are limited to data analysis.
  - 9) Continuing review of research, not conducted under an IND application or IDE, 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.