

1. **Clinical studies of drugs and medical devices** *only* when condition (a) or (b) is met.
 - 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 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. from healthy, non-pregnant 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 other adults and children, 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:

 - hair and nail clippings in a non-disfiguring manner;
 - deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
 - permanent teeth if routine patient care indicates a need for extraction;
 - excreta and external secretions (including sweat);
 - 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;
 - placenta removed at delivery;
 - amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
 - 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;
 - mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
 - 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: (see next page)

- 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;
- weighing or testing sensory acuity;
- magnetic resonance imaging;
- electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
- 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:**

- a. have previously been collected (retrospective) for nonresearch purposes
- b. have previously been collected (retrospective) for research purposes, provided the materials were not collected for the currently proposed research
- c. will be collected (prospective) solely for nonresearch purposes¹

(NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(4\)](#). 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 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.)

8. **Continuing review of research previously approved** by the convened IRB as follows:

- a. where
 - 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
- 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.

¹ [2007 Federal Register](#)

13. UCI Expanded Category of Minimal Risk Research Procedures: Skin Punch Biopsy for Children and Adults

- a. The following limitations apply to the use of this expanded expedited category:
 - i. **The research is not federally funded and not subject to FDA regulations.**
 - ii. **The biopsy must be no greater than 2 mm.**
 - iii. A biopsy greater than 2 mm requires full committee review.
 - iv. If multiple 2 mm skin punch biopsies are proposed, the IRB will consider whether the procedures in totality rise to a level greater than minimal risk on a case by case basis.
 - v. Placement of biopsy must be on the upper inner arm, upper inner thigh, or lower back/upper buttock below the pant line. The location must be agreed upon by the parent or legally authorized representative, the child subject or adult subject, in consultation with the lead researcher.
 - vi. Additional considerations for children:
 1. **If the child is not affected by the condition under study, s/he must be age 7 or above to allow for assent. Parental permission is required.**
 2. **If the child is affected by the condition under study, there is no age restriction. Parental permission is required.**
- b. Additional guidance for researchers (the following text may be included in the IRB submission when describing the procedure):
 - i. Use of EMLA or similar topical numbing cream should be used at least 2 hours in advance of the procedure for minors. Then, after selecting a biopsy site on the upper inner arm, upper inner thigh, or lower back/upper buttock the area will be cleansed with an antiseptic solution. Lidocaine or other local anesthetic will then be infiltrated into the biopsy area by injection to provide local anesthesia. A single 2 mm piece of skin will be removed via punch biopsy. A sterile gauze pad will be placed over the site to control bleeding, and the site will be bandaged. The biopsy site may be closed with a stitch if desired. The participant (and/or their parent) will be provided with post-biopsy care instructions.