Can My Study Be Expedited?

These are the expedited review research categories determined by the Office of Human Research Protections 45 CFR 46.110. The IRB will make the determination if the research presented qualifies for expedited review.

1. **Clinical studies of drugs and medical devices only when the following conditions are met.**
    a. Research on drugs for which an investigational new drug application is not required.
    b. Research on medical devices for which an investigational device exemption application is not required; or the medical device is approved for marketing and is being used in accordance with its 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. 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.
    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:**
    a. Hair and nail clippings in a non-disfiguring 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. Examples:**
    a. Physical sensors 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 subjects 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).**

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. Where research is permanently closed to enrollment of subjects, all subjects have completed research related interventions, and the research remains active for only long term follow of of subjects.

    b. No subjects have been enrolled and no additional risks have been identified.

    c. 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.

Source: http://www.hhs.gov/ohrp/policy/expedited98.html