Expedited Criteria

Research proposals that can be considered for expedited review process are those that have the following characteristics:

1. Method of research carries low risk to the subjects or less than the "minimal risk", which is no more than the risk in everyday life, such as getting pricked by a needle while sewing or repairing the cloth fabric.
2. If there is a risk of invading subject's privacy that it may reveal the secrets of the subject, the researcher has already taken appropriate measures to prevent the risk so that it is not more than the "minimal risk".
3. Collecting materials obtained from therapeutic procedures, for example, moles, warts, and lipid lumps that have already been excised for research requires informed consent.
4. Blood collection is done by using a needle pricking the fingertip, heel, ear, or venous blood taken from healthy adult subjects who are not pregnant with their body weight not less than 50 kilograms. The volume of the blood taken must not exceed 550 milliliters within 8-week period and drawn no more than 2 times per week.
5. In collection of blood samples from adults whose condition is other than that described in 5 or from children, this can be done only after considering the age, weight and health of the subject. The blood volume taken must not exceed 50 milliliters or 3 milliliters per 1 kilogram of body weight within 8 weeks and no more than 2 times a week.
6. Biological specimen collection in advance for research must use noninvasive methods, such as cutting hair, cutting nails in a way that they do not damage the beauty, teeth obtained from normal extraction treatment, exudates, such as sweat, placenta collected after birth of a baby, amniotic fluid obtained from ruptured amniotic sac or during birth, skin cells collected by scraping skin, mucous cells collected by buccal swab, mouth washing, sputum collected after saline spray, etc.
7. Data collection of noninvasive procedures without sedation, sleeping pill. (If medical devices are employed, only authorized medical instruments for general use are allowed.) For example, physical sensors that uses energy sensors to contact the patient without invading the body (except for x-rays or microwaves) such as magnetic resonance imaging (MRI), ECG, EEG, ultrasound, Doppler blood flow, echocardiography, moderate exercise in healthy volunteer, body composition measurement.
8. Uses of data, records, documents, specimens already collected for non-research purposes such as diagnosis or treatment (leftover specimens).
9. Data collection from audio records, video records or research images.
10. Researches on human behaviors involving a single person or groups of people or surveys, history taking, focus group interview, program evaluation or methods regarding quality assurance.
11. Conducting continuing review of a research project that has already been approved or consideration of a progress report that does not enroll new subjects and interventions that is used in the research study which is completed without additional risk, including analyses of old data in a new context.
12. If the research project has been reviewed and approved, and the researcher wants to submit its "minor change" which means that the change does not increase the risk of the subject, no change in research methodology, no change in the inclusion / exclusion criteria.

Reference

1. DHHS 45 CFR 46.110
2. FDA 21 CFR 56.110