EXPEDITED REVIEW CATEGORIES

The Department of Health and Human Services (HHS) has established and published a list of categories of research that may be reviewed by the IRB through an expedited review procedure. Research that falls under an expedited category is not reviewed by the full board at its monthly meetings, but is reviewed by the IRB on a rolling basis. Expedited review can be considered when research activities present no more than minimal risk to human subjects and involve only procedures listed in one or more of the following nine categories or for minor modifications to previously approved research.

Note that research involving greater than minimal risk or prisoners does not qualify for expedited review.

Expedited Review Category #1

Clinical studies of drugs and medical devices only when:

- Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required.
- 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.

Expedited Review Category #2

Collection of blood samples by finder stick, heel stick, ear stick, or venipuncture 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.
- Other adults 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.

Expedited Review Category #3

Prospective collection of biological specimens for research purposes by noninvasive means.

Expedited Review Category #4

Collection of data on subjects 18 years of age or older through noninvasive procedures routinely employed in clinical practice, excluding procedures involving x-rays or microwaves as well as procedures involving general anesthesia or sedation. Where medical devices are employed, they must be cleared/approved for marketing.

Expedited Review Category #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.

Expedited Review Category #6

Collection of data from voice, video, digital, or image recordings made for research purposes.

Expedited Review Category #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, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Expedited Review Category #8

Continuing review of research previously approved by the entire IRB as follows:

- 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.
- Where no subjects have been enrolled and no additional risks have been identified.
- Where the remaining research activities are limited to data analysis.

Expedited Review Category #9

Continuing review of research in which 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.

Revised January 21, 2019